FLASHTEST

Version No.: V1.0

INSTRUCTION FOR USE

Real-Time qPCR System
(for veterinary use)

Model: QPCRV1600

WUXI OPULEN TECHNOLOGY CO., LTD.

Disclaimer

To ensure proper usage of the nucleic acid extractor, operators must strictly adhere to the instructions outlined in the "Instruction for Use". Failure to comply with these instructions may compromise the instrument's protective capabilities and result in damage.

Manufacturer

Name of registrant/manufacturer: Wuxi Opulen Technology Co., Ltd

Manufacturer Address: Blk 6,100 Dicui Rd.Wuxi, China

Manufacturer Website: flashtestbio.com

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Chapter 1 Safety Precautions

1.1 Definition of Symbols

Symbols in the"Instruction for Use":

Warning: Failure to follow the specified procedures or instructions may result in physical injury or damage to the instrument.

High Temperature: potential heat damage on the surface of the instrument.

Biohazard: Caution must be taken when working with substances that may carry an infectious risk.

Symbols on the instrument:

Read the Instruction for Use Carefully: found on the nameplate.

Biohazard: near the nameplate
near the PCR tube wells

High Temperature: near the thermal module

Serial Number: on the nameplate

Refer to Instruction for Use: on the nameplate

1.2 Operation Requirements

The Real-Time qPCR System should be operated by properly trained personnel.

• This instrument is an electromechanical device. Failure to strictly adhere to the operating instructions may result in potential hazards, including electric shock or physical injury to the user. Therefore, it is crucial to strictly follow the guidelines.

• Operate the instrument exclusively in accordance with the provided safety prompts.

• Replace fuses as instructed in the "Instructions for Use." Avoid disassemble the instrument or replacing any other components, as unauthorized

disassembly or repair will void the warranty.

- Only manufacturer technicians are authorized to repair the instrument.
- Do not open the heated lid while the instrument is in operation.

Install the instrument indoors:
- in an area with good ventilation
- away from corrosive gases and strong magnetic fields
- shielded from direct sunlight
- within required temperature and humidity levels

- Operate the instrument indoors under the following conditions:
  - Temperature: 10°C to 30°C
  - Relative humidity: ⩽ 80%
- When handling samples, wear eye protection, appropriate clothing, and gloves.
- When shipping instrument for repair, disinfect the instrument first, then proceed to shipping.

- Right after testing, avoid touching the thermal modules of the instrument to prevent burns。

1.3 Electrical Safety

- Connect the instrument to a grounded outlet that compiles with safety regulations and supplies 100-240V AC, 50/60Hz power.
- Ensure the power supply matches the instrument's voltage and frequency requirements.
- Turn off the power before connecting the power cord.
- Avoid touching the power switch or cord with wet hands.
- Avoid unplugging the power cord while the instrument is powered on.
- Avoid cleaning the instrument while it is powered on.
- Avoid replacing fuses while the instrument is powered on.
- Turn off the power when the instrument is not in use.
- If a power outage occurs during operation, restart the operation after power is restored.

1.4 Electromagnetic Compatibility

- The manufacturer provides electromagnetic interference precautions to customers and users.
- The user must make sure the installation environment of the instrument complies with the electromagnetic interference precautions.
- This instrument has been tested and meets the EN 61236 standard (group1, class B).
- It is recommended to assess the electromagnetic interference before installing the instrument.
- Avoid using this instrument in close proximity to sources of strong electromagnetic radiation, as it may disturb its proper operation.

Chapter 2 Overview

This product utilities Fluorescent Polymerase Chain Reaction (PCR) and is designed for use in conjunction with the matching nucleic acid detection kit. It enables quantitative and qualitative detection of animal-derived nucleic acid samples (RNA/DNA) for veterinary diagnosis.

Chapter 3 Technical Specifications

3.1 Name and Model

The Real-Time qPCR System (hereinafter referred to as the "instrument") is manufactured by Wuxi Opulen Technology Co., Ltd. (hereinafter referred to as the "company"). The model number is QPCRV1600.

3.2 Intended Use

This product is designed for veterinary laboratory tests. It should be used with compatible PCR kits.

3.3 Operating Principle

Used in conjunction with compatible reagents, this product operates under a set of parameters and utilizes the control system and temperature control module to provide the required temperature environment for RNA reverse transcription, denaturation, annealing, extension, amplification, and melting of nucleic acids in vitro. The photodetection module collects real-time fluorescence signals generated during the amplification process, and the software analyzes and processes the data for amplification and analysis of specific target genes or nucleic acid sequences in the sample.

3.4 Technical Parameters

Basic performance	Specification
Sample capacity	16 x 0.2mL PCR tubes
Reaction volume	20μL ~ 100μL
Reaction volume	F1: FAM, SYBR Green I F2: HEX, VIC, JOE F3: ROX, TEXAS RED F4: Cy5
Thermal module temperature range	10°C～ 100°C
Uniformity	⩽ 1°C

Thermal control accuracy	⩽ 0.5℃
Heating rate (average)	⩾ 4.5℃ /s
Heating rate (max.)	⩾ 6.5℃ /s
Cooling rate (average)	⩾ 3.2℃ /s
Cooling rate (max.)	⩾ 5.1℃ /s
Heated lid temperature range	30℃～ 120℃
Fluorescence intensity detection repeatability	CV ⩽ 3%
Sample detection repeatability	CV ⩽ 3%
Sample linearity	Linear regression coefficient r ⩾ 0.99
Fluorescence linearity	Linear regression coefficient r ⩾ 0.99
Display	10.1 inch touch screen
Power supply	Rated power supply voltage: 100-240VAC Rated power supply frequency: 50/60Hz Rated power: 800VA
Ports	USB 2.0, Ethernet, RS-232
Dimensions	Width 300mm x Depth 370mm x Height 190mm
Weight	10.4Kg

3.5 Instrument Composition

The Real-Time qPCR System is composed of control system, photoelectric system, thermal module, heated lid, casing components, and software system.

The schematic diagram of the structure is shown in Figure 3.5.1:

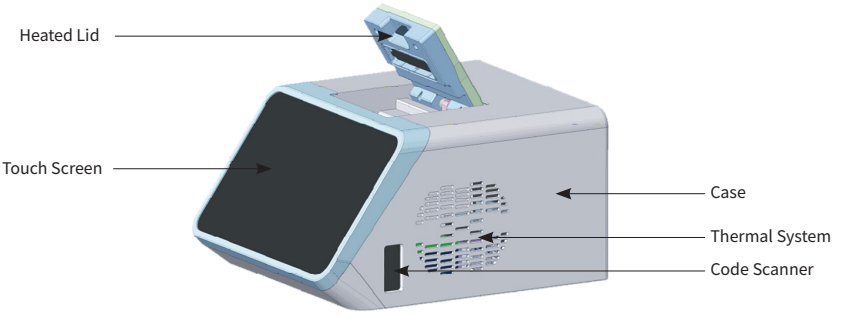


Figure 3.5.1

At the rear of the instrument, there are three USB ports, one Ethernet port, one RS-232 port, one power switch, and one power socket, as illustrated in Figure 3.5.2:

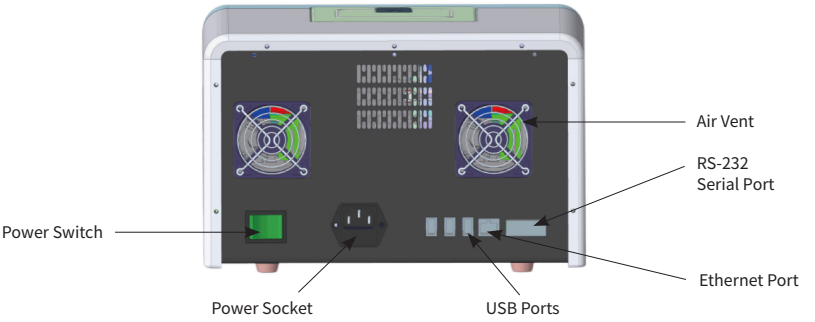


Figure 3.5.2

The system diagram is demonstrated in Figure 3.5.3:

System Schema

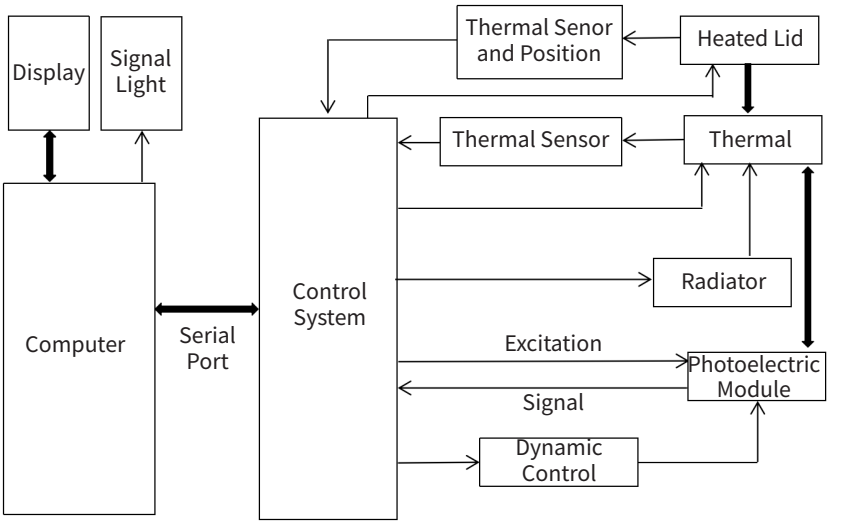


Figure 3.5.3

Main functional modules	Module Description
Heated lid component	Keeps temperature of the tube lid higher than the tube body, to prevent condensation on the lid.
Thermal cycling component	Thermal cycling component includes heating module, cooling modules, and sensors. They create the thermal cycles in the system.
Photoelectric system	Collects florescence signal during the amplification process.
Control system	Works between the human-computer interface and other PCR test modules.
Control panel	The control panel is the human-computer interface
Barcode scanner	Scans sample information.

3.6 Software

(1) Name: Real-Time qPCR System.

(2) Model: QPCRV1600.

(3) Release Version: Ver1.

(4) Version Naming Convention: Our official naming convention adheres to the format "VerX.Y.yyyymmdd" where all parts are digits.

X: major software updates involving the addition of multiple modules, architecture changes, or comprehensive functional updates;

Y: minor software updates involving minor function updates

yyyymmdd: updates that includes bug fixes or minor updates.

(5) Software Quality Requirements:

• Performance efficiency: ensure page loading and switching time is under 2 seconds.

• Security prompts: Provide appropriate prompt such as "login failed" or "Please check the entered serial number and credentials"

• Reliability: Enable automatic system restart and software service recovery when the system malfunctions.

• Compatibility: Supports ARM architecture Android (version 5.1.1) platform.

• Application: the application can be uninstalled and installation on other devices.

• Database backup and recovery: automatic database backup and restoration with backup files from the disk.

• User interface: Include menu, window, function keys.

• User interface types: Include command interface, program interface, and graphical interface.

• Authentication: the product usage is limited to authenticated users only.

• Error notification: Prompt users with relevant information when encountering errors.

• Software version and updates: Display model and version number information on the login interface.

• System load pressure risk: When system is under high load pressure, temporary service unavailability may occur, including system errors or data loss.

• System risk: damage to hard disk damage may result in data loss; deletion of system authorization files may cause system inaccessibility.

• The system LOG, includes system error logs and service logs, which logs the system operational status.

3.7 Classification

Classification Categories:	Level
Electric shock protection classification	Over-voltage category: Category II
Pollution level	Level 2
Electromagnetic compatibility classification	Group 1, Class B

3.8 Contraindications

This instrument is intended for in vitro diagnostic use only and has no contraindications.

3.9 Service Life

• Lifespan: 5 years (excluding human damages).

• Production date: please refer to the nameplate.

• Please dispose obsolete instruments and accessories following local laws and regulations.

The instrument’ s lifespan compiles with GB/T 34986-2017 "Accelerated Product Testing Procedure". The instrument should be maintained and repaired following the guidelines outlined in the Instructions for Use. After maintenance, servicing, and repairs, products that have been confirmed to maintain basic safety and effectiveness can be used as designed.

3.10 List of Accessories

Please refer to the instrument packing list for details.

Chapter 4 Instrument installation

4.1 Transportation and Storage

(1) Transportation

The instrument is delicate and requires careful handling. For short-distance indoor transportation, packaging may not be necessary. For vehicle transportation, always use the original packaging and ensure all packaging materials are retrained. During transit and handling, protect the instrument from moisture, shocks, and inversions. Handle it with caution keep it in a horizontal position, and avoid exposure to strong impacts, rain, and sunlight. Transport under the following conditions:

- Temperature: -20°C to 55°C
- Relative humidity: below 90%
- Atmospheric pressure: 75 kPa to 106 kPa

(2) Instrument Storage Requirements

Store the instrument indoors under the following conditions:

- Temperature: -20°C to 55°C
- Relative humidity: ⩽ 90%
- Atmospheric pressure: 75 kPa to 106 kPa
- Location with good ventilation
- Avoid corrosive substances

4.2 Requirements for Usage Environment

4.2.1 Use Location

- Low humidity and minimal dust presence
- No water sources such as pools or pipes nearby
- Good ventilation and absence of corrosive gases and strong magnetic fields
- Keep within specified temperature and humidity levels
- The instrument's openings serve ventilation purposes, and it is crucial not to obstruct or cover these ventilation outlets. When operating the instrument, maintain a minimum space of 30cm on both sides and at least 20cm at the back of the instrument. In the case of operating multiple instruments simultaneously, ensure that the distance between each instrument is not less than 50cm.

• High temperatures can adversely affect the instrument's detection performance and may lead to malfunctions. Avoid using the instrument in direct sunlight or near strong light sources as it can interfere with fluorescence detection. Keep the instrument away from heaters, stoves, and other heat sources.

Do not place anything over the ventilation during operation.

4.2.2 Operating Environment

• Power supply: 100-240VAC, 50/60Hz.

• Ambient temperature: 10°C to 30°C.

• Relative humidity: not greater than 80%.

• Atmospheric pressure: 86 kPa to 106 kPa.

• Suitable for indoor use at altitudes below 2000m.

• Keep away from mechanical vibration and shock.

• Avoid exposure to strong electromagnetic field interference.

• Proper grounding is required.

4.3 Unpacking

Upon unpacking:

1. Examine the packaging for any signs of damage and promptly report any issues identified.

2. Verify all items against the packing list to ensure completeness.

3. Make note of any damaged or missing items for efficient after-sales support.

This procedure ensures secure transportation and streamlines the after-sales service process.

Packing list

No.	Item	Specifications	Quantity
1	Real-Time qPCR System	QPCRV1600	1
2	Power cord	EU standard, 250V, 10A	1
3	Fuse	Φ5×20mm - F10AL250V	2
4	Dust cover	-	1
5	Dust-free cloth	-	1
6	Air blower	-	1

7	Instruction for Use	-	1
8	Quick start guide	-	1
9	Certificate of conformity	-	1
10	Warranty card	-	1
11	Packing list	-	1

If the product sustains significant damage during shipment, refrain from using it. Please contact customer service immediately to seek assistance and resolve the issue.

4.4 Removing the Transport Lock

Upon unpacking, it is essential to remove the transport lock before powering on the instrument.

The transport lock is designed for transportation and secures the detection head to prevent damage from collisions during transit. Refer to Figure 4.4.1 and follow the instructions below to remove the transport lock before operating the instrument:

1. Ensure the instrument is powered off.

2. Turn the screw counterclockwise by hand until it is fully removed.

3. Please retain the transport lock screw for future use.

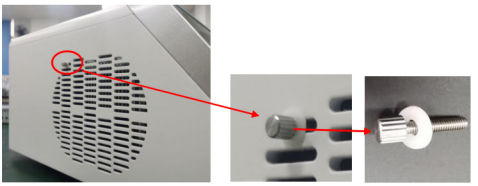


Figure 4.4.1

4.5 Instrument Installation

1.Remove the transport lock, then place the instrument following the requirements outlined in section 4.2.1.

2.Connect the supplied power cord to an outlet.

3.Power on the instrument by turning the power switch to the " I " position.

4.To power off, switch the power switch to " O " , and disconnect the power cord.

4.6 Network Security Guidelines

To minimize the risk of unintended instrument operation due to unauthorized access, malicious software intrusion, or network attacks, adhere strictly to the following requirements:

It is recommended to set up a screen lock (pattern or password) for enhanced security. For detailed instructions, contact the after-sales engineer.

Note:

1.Do not disable or uninstall the pre-installed security software on the instrument without authorization.

2. Refrain from connecting to unrecognized Wi-Fi networks.

3. Use flash drives approved by the manufacturer.

4.Avoid using flash drives from unrecognized sources.

4.7 Connecting to FLASHTEST Report Printing System

The instrument can be connected to the FLASHTEST Report Printing System via Ethernet or WiFi. This enables uploading of test results from the instrument to the computer. For further details, please get in touch with the after-sales engineer.

4.8 Software Update

The instrument's software can be updated over the air. For details, please contact the after-sales engineer.

Chapter 5 Instrument operation settings

5.1 Pre-startup check

Before powering on the instrument, please ensure the following:

・Verify that the power supply meets the system requirements.

・Confirm that the power cord plug is correctly and securely inserted into the power socket.

・Check if the working environment and placement conditions of the instrument meet the specified requirements.

5.2 Boot-up Interface

Upon completing the boot-up process, the instrument enters the login screen. User can log in using either the administrator account or a regular user account (the regular user account must be created in user management function).

The initial password for the administrator account is "12345". Press"Log in" to log in or press"Exit system" to exit the software, as illustrated in Figure 5.2.1:

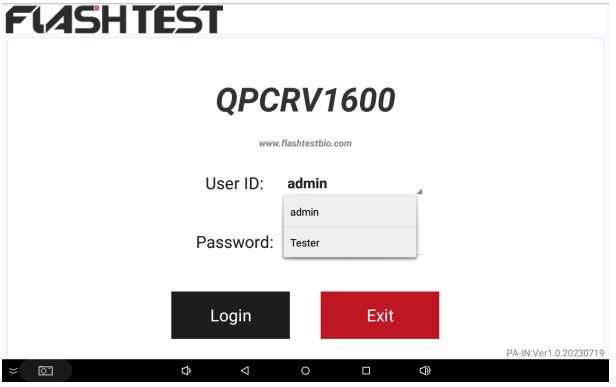


Figure 5.2.1

5.3 Software System Introduction

5.3.1 Introduction to the home interface

The home interface is shown in Figure 5.3.1.1.

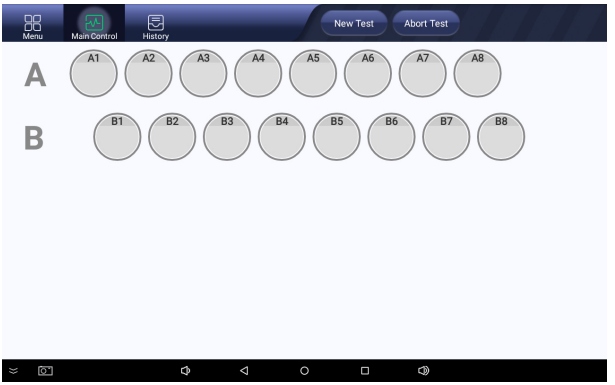


Figure 5.3.1.1

The software has three main tabs:

Figure 5.3.1.2

Menu: for configurations

Figure 5.3.1.3

Main Control: for testing operations

Figure 5.3.1.4

History: for test history

5.3.2 Introduction to Menu Interface

5.3.2.1 Menu Tab

After logging in with the administrator account, the menu interface has two settings: System Settings and User Management, as shown in Figure 5.3.2.1.1:

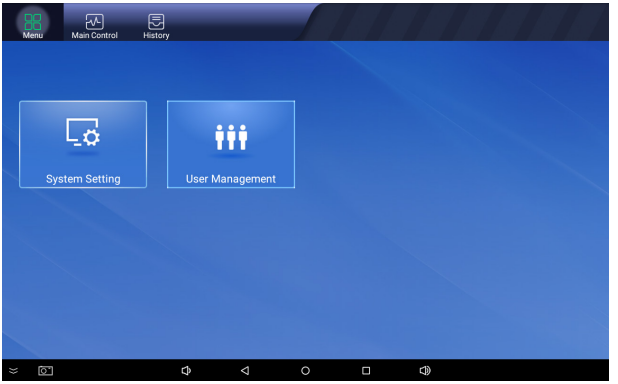


Figure 5.3.2.1.1

System Settings: As shown in Figure 5.3.2.1.2:

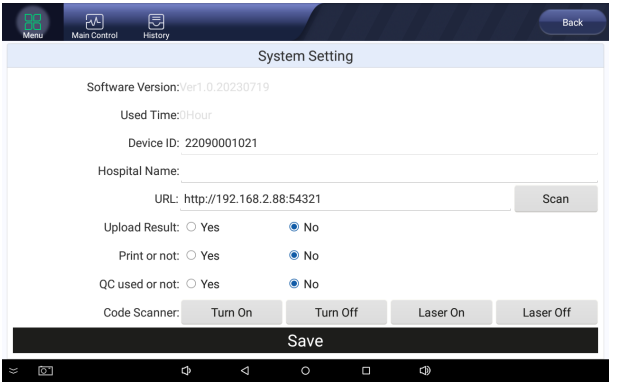


Figure 5.3.2.1.2

Software version: current software version

Usage time: Accumulated usage time of the instrument.

URL: Network address to which the instrument is connected to.

Device ID: ID number of the instrument.

Hospital name: Name of the hospital.

Upload results: The test results can be uploaded to a specified network address (URL).
Yes: enable the result upload function; No: disable the result upload function.

Print: The instrument can print the test result s through an external printer.
Yes: Print the test results; No: Do not print the test results.

PCR Control: use positive (PPC) or negative (NPC) PCR controls.

Yes: enable PCR Control features; No: disable PCR Control features.

Code Scanner: Barcode scanner settings.

Turn on: turn on light of scanner;

Turn off: turn off light of the scanner;

Laser on: Enable the barcode scanner;

Laser off: Disable the barcode scanner.

Save: Save settings.

User Management: create, modify, and delete account information for regular users (not for the administrator account):

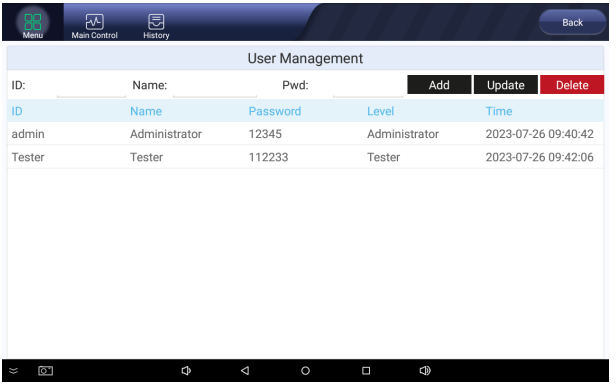


Figure 5.3.2.1.3

Add: add a new user.

Update: Select a user for editing, make modifications, then press update to save.

Delete: Select the user to be deleted, and press delete to remove the user.

5.3.2.2 Menu Interface for Regular User Login

After logging in as regular user, the menu interface has two buttons: System Settings and User Management, as shown in Figure 5.3.2.2.1:

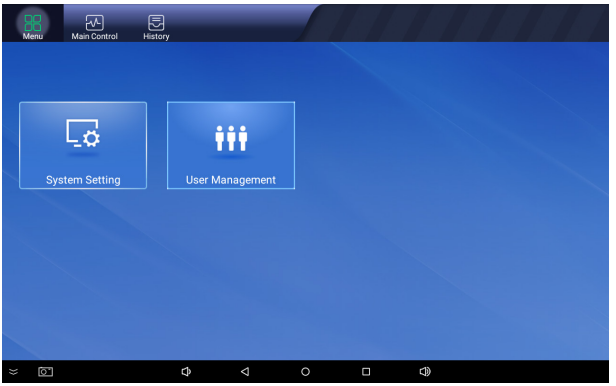


Figure 5.3.2.2.1

System Settings: As shown in Figure 5.3.2.2.2:

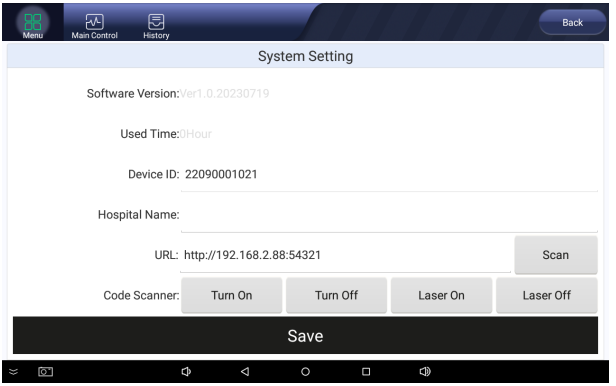


Figure 5.3.2.2.2

Software version: current software version.

Usage time: accumulated usage time of the instrument.

URL: network address the instrument is connected to.

Device ID: ID number of the instrument.

Hospital name: name of the hospital.

Upload results: The test results can be uploaded to a specified network address (URL).

Code Scanner: Barcode scanner settings.

Turn on: turn on light of scanner;

Turn off: turn off light of the scanner;

Laser on: Enable the barcode scanner;

Laser off: Disable the barcode scanner.

Save: Save the settings information.

User Management: This interface allows you to modify account information for regular users, as shown in Figure 5.3.2.2.3:

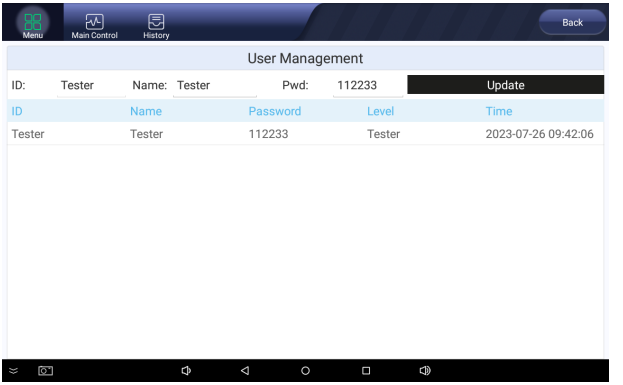


Figure 5.3.2.2.3

Update: Select a user for editing, make modifications, then press update to save.

5.3.3 Main Control Tab

The test interface allows you to select the detection wells, enter sample details, and start or abort test. There are 16 wells, consisted of 8 wells in row A (A1-A8) and 8 wells in row B (B1-B8), as shown in Figure 5.3.3.1:

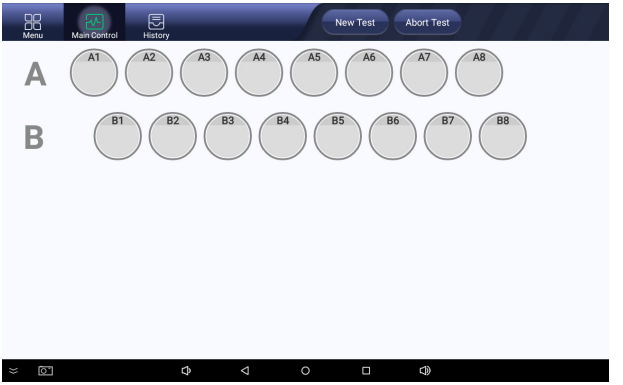


Figure 5.3.3.1

Figure 5.3.3.2

New Test: create a new test

Figure 5.3.3.3

Abort Test: abort the running test

5.3.4 History Tab

The history interface allows you to view, upload, and export (print) the test results, as shown in Figure 5.3.4.1:

Figure 5.3.4.1

Figure 5.3.4.2

New Test: create a new test

Figure 5.3.4.3

Send Report: send selected test results to specified network address (URL).

Figure 5.3.4.4

Export: Export the test result data to a flash drive. The default export path is: "QPCR" folder in the root directory of the flash drive. Export file format is CSV.
If print test function is enabled in system settings, after restarting the instrument, this button will become "Print". Press "Print" to print the selected test results (the instrument needs to be connected to a compatible thermal printer).

To access the amplification curve of the sample, long-press the the test result serial number.

Swipe up/down to view curves from different projects.

Tap "Close." to exit this view. For editing the sample ID, press "Edit Sample ID."

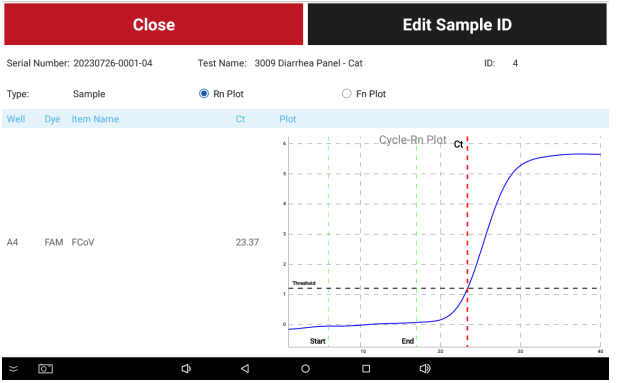


Figure 5.3.4.5

5.3.5 Heated lid status light

The table below illustrates the status of the heated lid status light:

Status	Light Color	Light Status	Illustration
After boot-up initialization	Blue	Always on	
During test	Green	Flashing	
After test	Green	Always on	

Chapter 6 Test Settings

6.1 Test Settings

① Press "New Test" on main control, as shown in Figure 6.1.1:

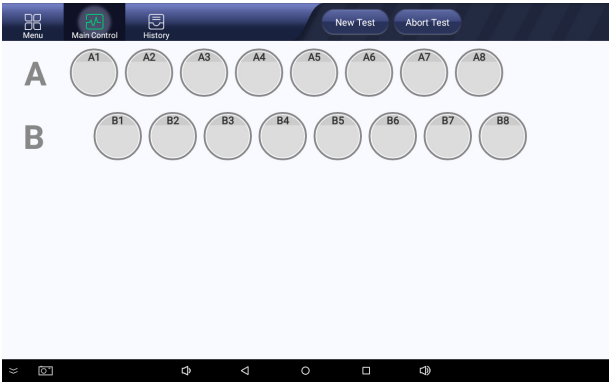


Figure 6.1.1

②Insert PCR tubes into the PCR wells, select category, panel, and test name, as shown in Figure 6.1.2:

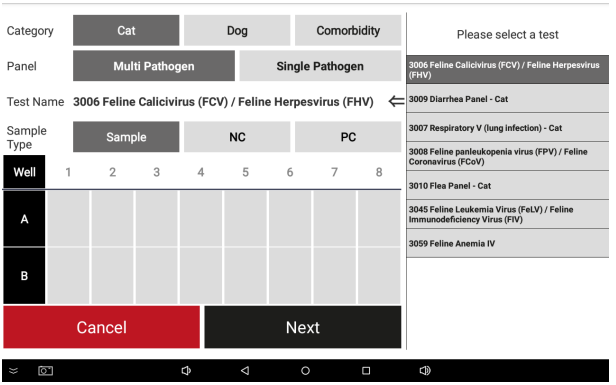


Figure 6.1.2

Sample

Sample: The well turns dark gray after selection.

Figure 6.1.3

NC

Negative Control: The well turns green after selection.

Figure 6.1.4

PC Positive Control: The well turns red after selection.

Figure 6.1.5

③ Select the corresponding well according to where the PCR tube is placed in the instrument, as shown in Figure 6.1.6:

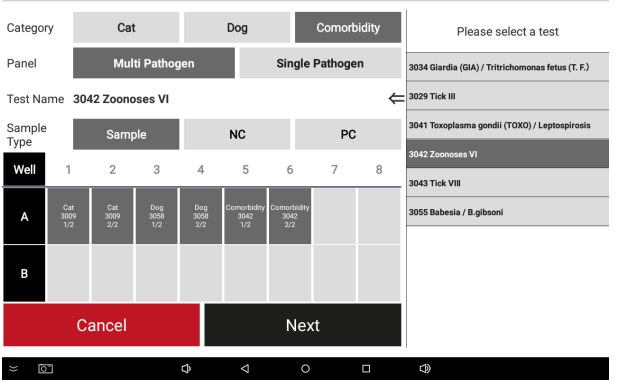


Figure 6.1.6

Cancel Cancel: cancel this new test.

Figure 6.1.7

Next Next: save new test settings, proceed to the next step.

Figure 6.1.8

④ (Optional) Set the sample descriptions corresponding to the PCR tube in wells. The sample information can be manually edited or scanned to enter, as shown in Figure 6.1.9:

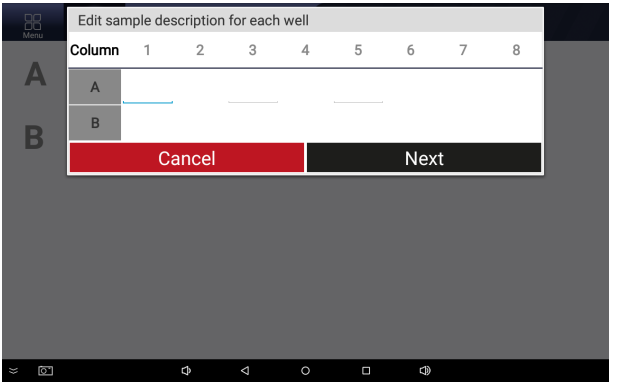


Figure 6.1.9

Cancel

Figure 6.1.10

Cancel: cancel this new test.

Next

Figure 6.1.11

Next: save new test settings, proceed to the next step.

⑤ Before starting the test, make sure that the heated lid is in a closed state, and do not open the heated lid during the detection process, as shown in Figure 6.1.12:

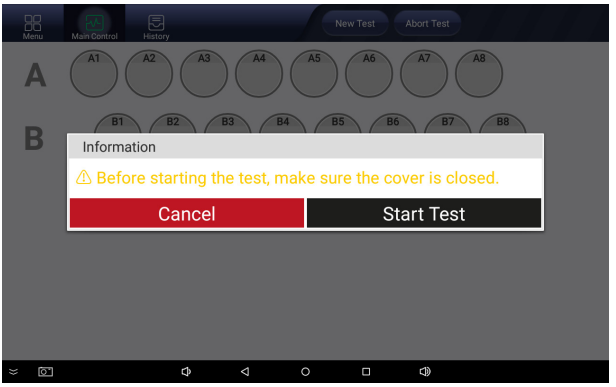


Figure 6.1.12

Cancel

Figure 6.1.10

Cancel: cancel this new test.

Start Test

Figure 6.1.11

Start Test: Start test.

6.2 Progress Monitoring

① The heated lid is preheated to set temperature. The main control interface display the progress of the heated lid's temperature change, as shown in Figure 6.2.1:

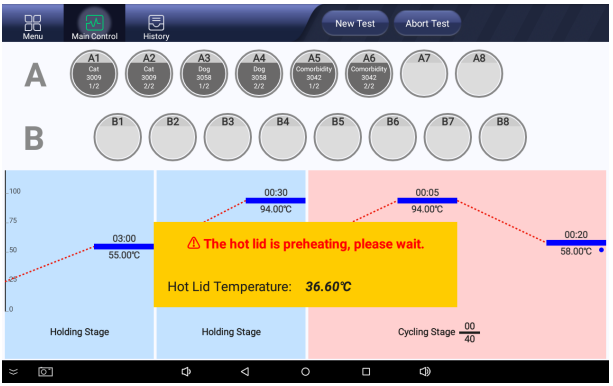


Figure 6.2.1

② Once the preheat is completed, the main control interface displays the test name in each well, test timer, and thermal cycle status in real time, as shown in Figure 6.2.2:

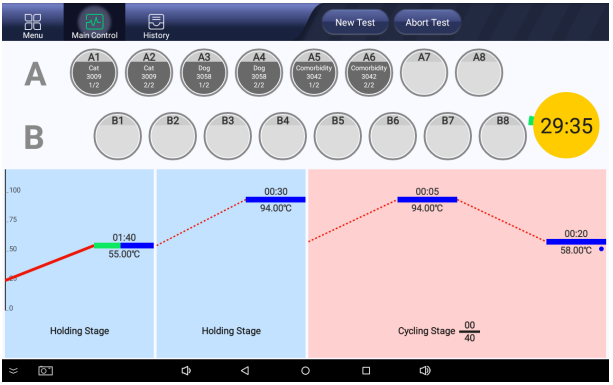


Figure 6.2.2

6.3 Results Query

① Once the test is completed, the test results shows in a popup window, as shown in Figure 6.3.1:

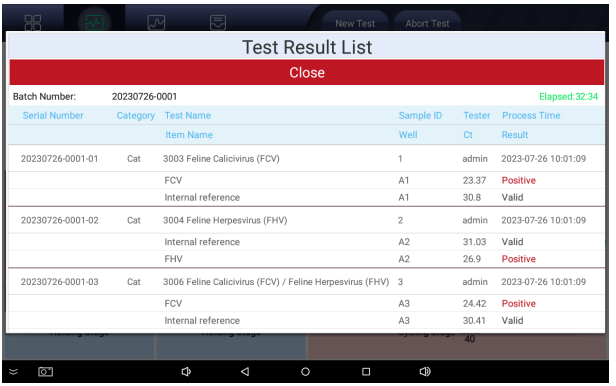


Figure 6.3.1

Close: exit this view.

Figure 6.3.2

② Test result are found in history, as shown in Figure 6.3.3. For detailed operations in the history interface, please refer to Chapter 5.3.4:

Figure 6.3.3

Note:

1. Never open the heated lid right after a test. Allow at least 5 minutes for the heated lid to cool down before opening, to prevent burns and PCR tube caps from popping off.

2. In case of a power outage during operation, the test must be restarted after power is restored. New samples should be prepared for testing. Samples from the interrupted test cannot be used again, because the result would be invalid.

6.4 Report Printing

The instrument uploads test results to a the FLASHTEST Report Printing System for printing, via Ethernet or WiFi. Test reports can be printed from the desktop system.

6.4.1 Device Connection

Ensure both the instrument and the computer are connected to the same Ethernet or WiFi network. Check the IP address of the computer and set the instrument's network address accordingly, following the instructions below:

1.Open the Run window using Win+R, type "cmd," and click "OK."

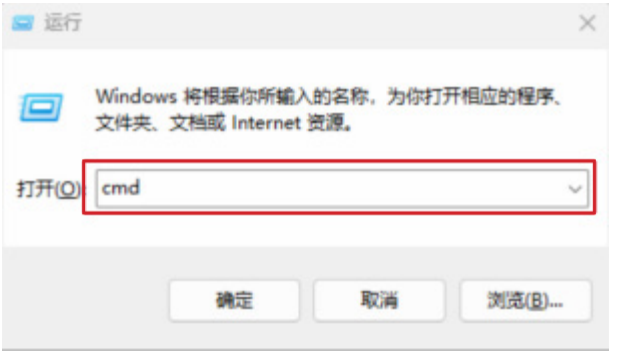


Figure 6.4.1.1

2.Enter "ipconfig" in the pop-up interface, as shown in Figure 6.4.1.2, and press Enter.

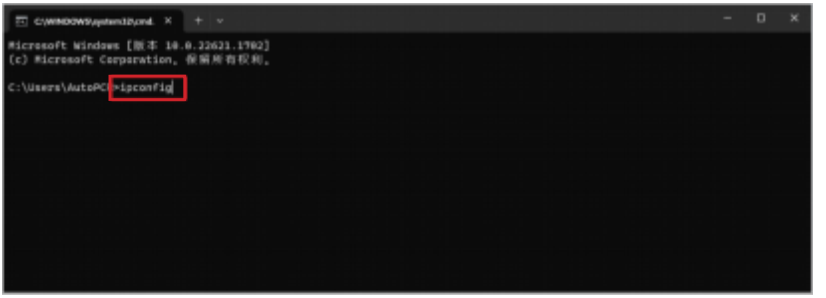


Figure 6.4.1.2

3.As shown in Figure 6.4.1.3, the IPv4 address in the current interface represents the IP address of the computer.

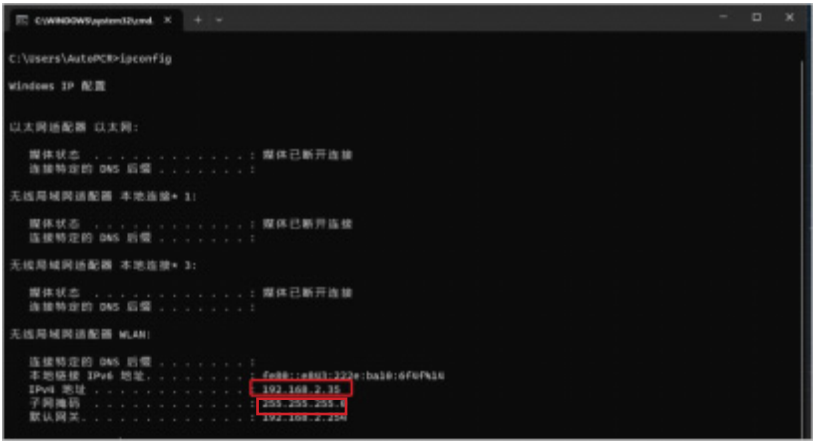


Figure 6.4.1.3

④ As shown in Figure 6.4.1.4, in the instrument's system settings interface, configure the URL address to match the IP address of the computer, set the port number to 54321, and set Upload Results to "Yes". After making these setting, click "Save". Once the save is successful, exit the system, then log in again. The instrument will now be connected to the computer.

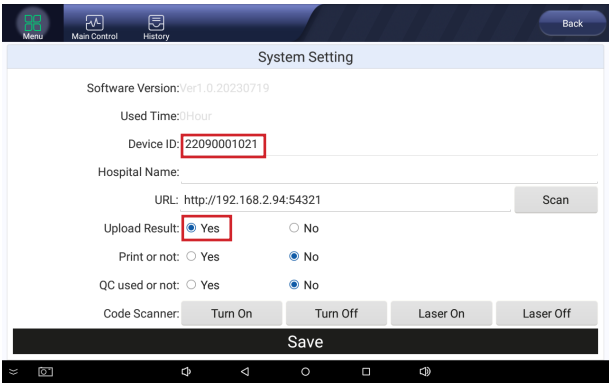


Figure 6.4.1.4

6.4.2 System Installation and Use

① To install the report printing system, double-click the installation program (FT-Report Setup) on computer. After successful installation, double-click the application (FT-Report) on desktop to open the application, as displayed in Figure 6.4.2.1. Once opened, input the appropriate account and password in the system login interface. The initial

password for the administrator account is 12345. Click "Login" to access the report printing system.

Figure 6.4.2.1

② On the left side of the report printing system page, there are four main menus: Home, Report System, User Management, and System Settings. Upon logging into the report printing system, the homepage is shown: Figure 6.4.2.2

Figure 6.4.2.2

③ Report System:

view and delete test reports, and preview test reports for printing.

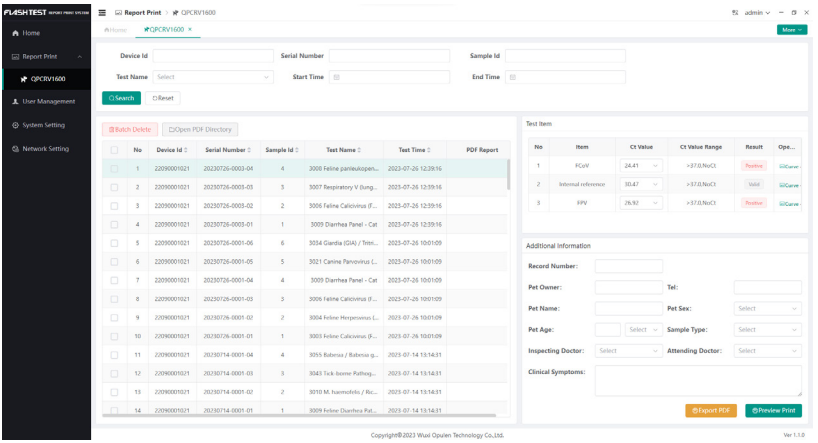


Figure 6.4.2.3

After the instrument completes a test, it automatically sends the results to the FLASHTEST Report Printing System. Upon receiving the result data, the system will display a prompt at the top of the page, as illustrated in Figure 6.4.2.4.

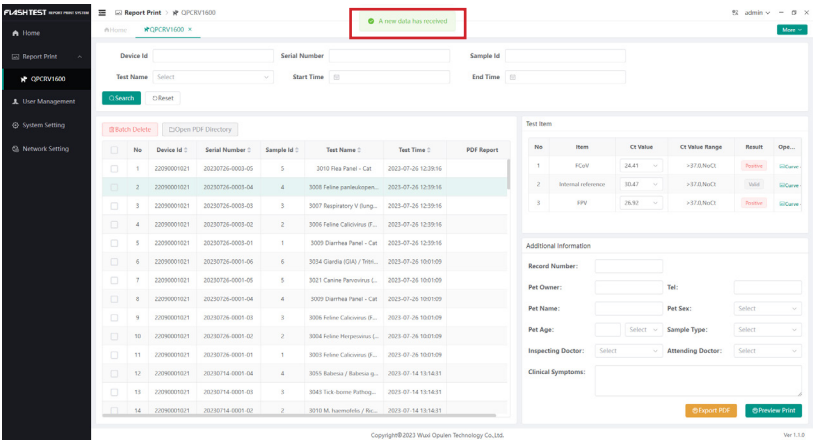


Figure 6.4.2.4

Press “Export PDF” to export test report.

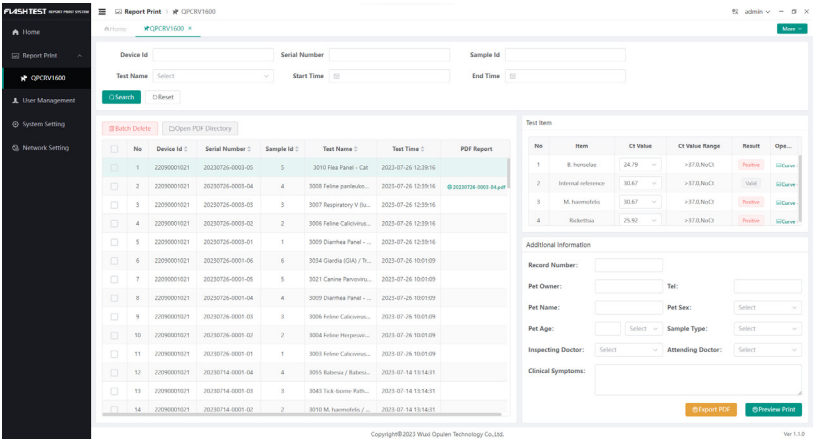


Figure 6.4.2.5

Press "Print Preview" in the test results on the report system page, as shown in Figure 6.4.2.6.

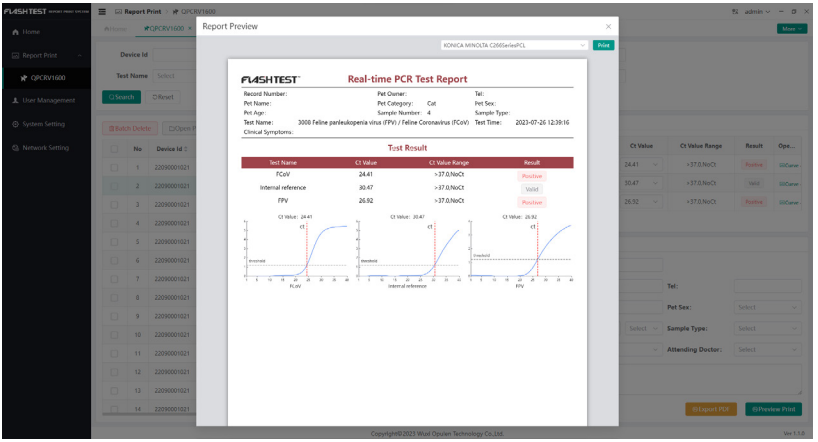


Figure 6.4.2.6

④ User Management: add, modify, and delete user accounts.

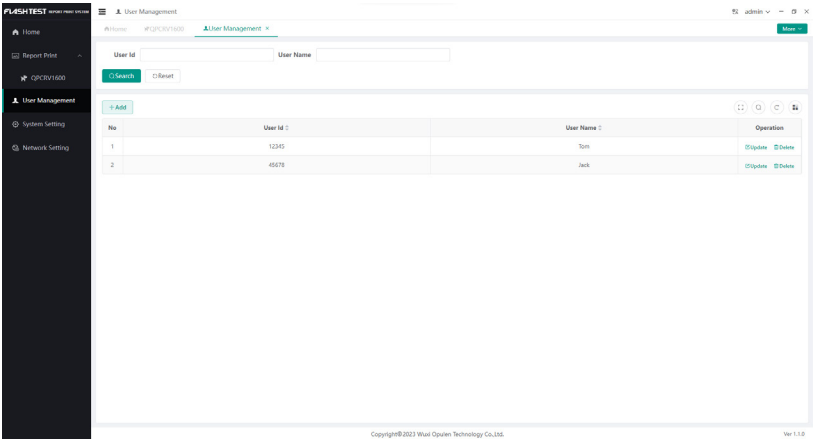


Figure 6.4.2.7

⑤ System Settings: manage hospital information.

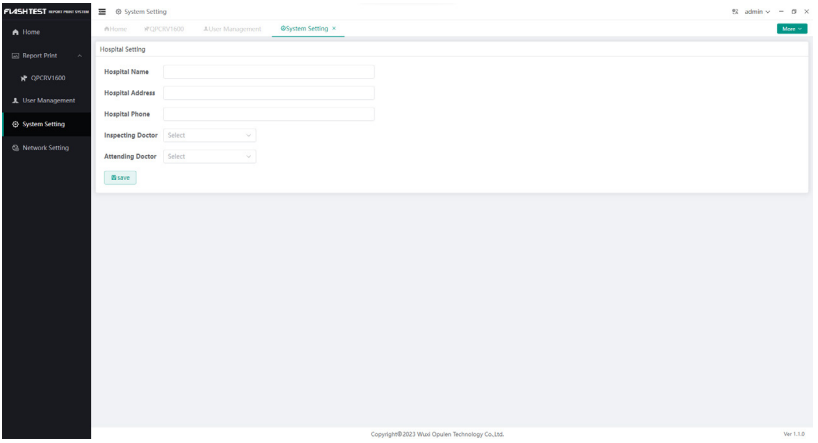


Figure 6.4.2.8

⑥ Network Setting：Make network configurations.

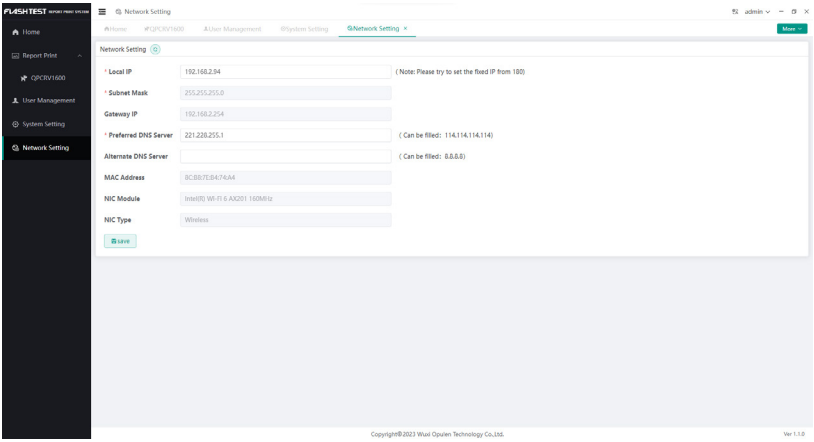

Network Setting
admin
Home
Report Print
QPCRV1600
User Management
System Setting
Network Setting
Home
QPCRV1600
User Management
System Setting
Network Setting
More
Network Setting
Local IP
192.168.2.94
(Note: Please try to set the fixed IP from 100)
Subnet Mask
255.255.255.0
Gateway IP
192.168.2.254
Preferred DNS Server
221.220.255.1
(Can be filled: 114.114.114.114)
Alternate DNS Server
(Can be filled: 8.8.8.8)
MAC Address
8C:88:7E:B4:74:A4
NIC Module
Intel(R) Wi-Fi 6 AX201 160MHz
NIC Type
Wireless
save
Copyright©2023 Wuxi Opulen Technology Co.,Ltd.
Ver 1.1.0

Figure 6.4.2.9

Chapter 7 Common Problems and Solutions

During the use of instruments, it is possible that some faults may arise, impacting their performance. This section provides common problems, potential causes, and suggested solutions to help address these issues.

Scenario	Cause analysis	Solution
The instrument cannot start	The power cable is not securely plugged	After securely plugging in the power cord, switch on the power by pressing it to the " | " position. Verify whether the indicator light is illuminated. If the indicator light is on, the issue is not related to the power supply, but it may be due to a device malfunction that necessitates repair.
Some test wells produce invalid results.	The test wells do not contain samples or quality control products.	Place samples or quality control products into the respective test wells.
Program exist abnormally.	Program malfunctions	Re-enter the program, or restart the instrument and then re-enter the program.
Results are abnormal	Sample error Device malfunction	Ensure that the samples are correct and error-free Device malfunction. Please contact technical support.
Measurement board hardware fails self-test during the startup process	AD chip soldering issue or damage	Hardware malfunction. Please contact technical support.
Temperature control board hardware fails self-test during the startup process	Loose connection of the temperature sensor wiring	Hardware malfunction. Please contact technical support.

The temperature remains unchanged for an extended period during the heating and cooling process of a normal project.	It is possible that the Peltier element is damaged. The program will report a detailed error in such a case.	Hardware malfunction. Please contact technical support.

For unknown issues:

- Document the scenario, behavior, and troubleshooting steps in detail.
- Share this information with technical support for technical support.

In the event of any instrument malfunction not listed above, discontinue usage immediately and promptly reach out to the after-sales support for assistance.

Chapter 8 Instrument Maintenance and Repair

8.1 Instrument Cleaning

1) Instrument Surface Cleaning:

Regularly wipe the instrument's surface using a soft cloth and a small amount of water, and then ensure it is thoroughly dried after cleaning. In case of any reagent leakage on the instrument's surface, clean it with a soft cloth and 75% alcohol.

2) Reaction Well Cleaning:

• Regularly clean the reaction wells to prevent dust or impurities from affecting PCR amplification and fluorescence detection. Gently blow air into the wells for cleaning, typically once every three months.

• To prevent dust from entering the reaction wells, always cover the instrument with a dust cover when it is not in use.

• If reagents enter the sample wells, wipe them clean with a lint-free cloth and 75% alcohol.

Before cleaning the instrument, it is necessary to turn off the power and unplug the power cord.

Do not pour liquids into the reaction module or inside the instrument. Do not use highly corrosive reagents or organic solvents to clean the instrument. If using disinfectants or cleaning agents not recommended by the manufacturer, please consult the manufacturer or their representative.

8.2 Protecting the instrument:

• Avoid frequent power on/off cycles. The interval time between two switches should not be less than 30 seconds.

• After completing an experiment, do not immediately turn off the power. Allow the instrument to remain in standby mode for 10 minutes (the internal fan will continue running), and power off the instrument when the module temperature returns to room temperature.

• Please use the power cord provided by the original manufacturer.。

If the instrument runs continuously for more than 10 hours, turn it off for 2 hours before restarting. Power off the instrument when not in use.

Avoid using the instrument for water baths or cooling (e.g., 4°C).

Maintenance personnel not from the original equipment manufacture are prohibited from unauthorized disassembly of the instrument.

8.3 Replacing Fuses

The instrument is safeguarded by two 10A fuses. To replace a blown fuse, follow these steps:

1.Turn off the power and disconnect the power cord.

2.Use a screwdriver to open the fuse box drawer.

3.Replace the fuse with a new one (Φ5×20mm - F10AL 250V).

4.Close and securely tighten the fuse box drawer.

5.Reconnect the power cord.

Before replacing the fuse, make sure to turn off the power and unplug the power cord.

8.4 Waste Disposal

After each experiment, there will be a large amount of amplified nucleic acid in the PCR tube, which should be handled promptly following relevant regulations to prevent any contamination of the laboratory and instrument.

After removing the PCR tube from the reaction module, avoid opening it to prevent potential contamination of the laboratory due to the high concentration of nucleic acid it may contain.

8.5 Overheating Protection

The instrument's heating system is equipped with an overheat protection device. In the event of a heating system failure where the temperature value exceeds the upper

limit of the allowable range, the protection device will automatically disconnect and cannot be restored. Consequently, the heating system will cease normal operation.

Upon encountering such an overheating system failure, users must discontinue using the instrument immediately and promptly contact the manufacturer for repair.

Chapter 9 After-Sales Service Organization

Company Name: Wuxi Opulent Technology Co., Ltd.

Address: Blk 6,100 Dicui Rd.Wuxi, China

Contact Information: 0510-85167117

Chapter 10 : Labels and Identification

10.1 Instrument Nameplate

The content, layout, and positions of the instrument nameplate label are shown in Figure 10.1.1:

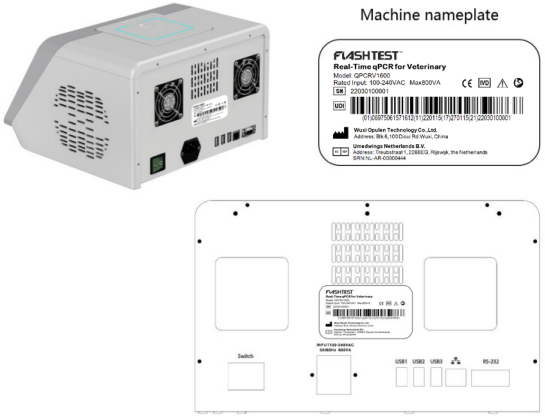


Figure 10.1.1

10.2 Packaging Label

The content, layout, and positions of the product packaging label are shown in Figure 10.2.1:

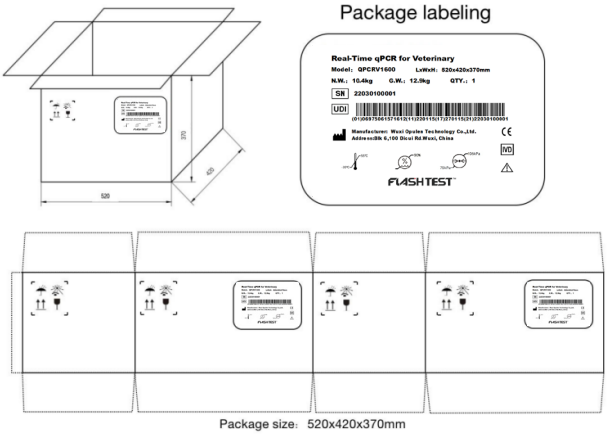
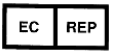
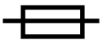


Figure 10.2.1

10.3 Other Labels

	Manufacturer		Lot number
	Attention, see instruction for use		Date of manufacture
	PCTB		Use until year & month (Expiration date)
	In Vitro diagnostic Medical device		Authorized representative in the European Community
	Serial Number		Unique Device Identifier
	CE mark		Refer to the user guide
	Keep dry		Keep away from sunlight
	Switch		Fuse

——————————END——————————

FLASHTEST