

USER GUIDE

Real time fluorescence
quantitative PCR Device

Model:OP-qPCR1600

Statement

The user should use the instrument strictly following this USER GUIDE. The instrument could get damaged, if not used as instructed.

Manufacturer



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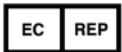


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Chapter 1: Safety Precautions

1.1 Symbol Definition

Symbols below are found in the User Guide:



Warning: potentially hazardous situation which may result in physical injury or damage to the instrument.



Caution, hot surface: marks a potentially hot surface.



Biohazard: indicates a situation of potential contact with biohazard.

Symbols below are found on the instrument:



Follow User Guide with Caution: found on the nameplate of the instrument.



Biohazard: found on the nameplate and area in contact with the test tubes.



Caution, hot surface: found next to the metal parts of the instrument.



In Vitro Diagnostic Medical Instrument: found on the nameplate of the instrument.



CE mark: found on the nameplate. Indicates this instrument is in compliance with the CE standard.

1.2 Precautions for Use

This instrument should only be operated by trained technical personnel.



- This machine is an electromechanical instrument. If not used strictly following the User Guide, it may cause electric shock or physical injury.
- Strictly follow the safety instructions when operating the instrument.
- The fuses can be replaced following the procedures in the User Guide. However, the warranty does not cover any damage, caused by unauthorized personnel opening the instrument or replacing any parts.
- The instrument should only be repaired by professionals of the manufacturer.
- Do not open the heated lid while the instrument is running.

- The instrument must be installed in a clean and ventilated indoor space.
- Avoid contact with any corrosive gas or strong magnetic fields.
- Avoid direct sunlight or strong light sources.
- Operate under specified temperature and humidity.
- Working temperature of the instrument is between 15°C and 30°C, indoors.
- Working humidity of the instrument is below 80%.



- Safety goggles and gloves must be worn when handling toxic, corrosive, or hazardous substances.
- Although the nucleic acids are purified, the operator shall guard against the potential hazards of biological substances.
- Follow local safety regulations when handling or disposing waste.
- In case of accidental spill or leakage, immediately sterilize with appropriate disinfectant, to prevent contamination.
- Damaged instrument must be sent to the manufacturer for repair. Sterilize the surface of the instrument, before shipping for repair.



- Do not touch metal parts to avoid burns, while the instrument is running, or shortly after experiments.

1.3 Electrical Safety

- To prevent electric shock, plug the instrument into a properly grounded receptacle (100-240VAC, 50/60Hz).
- Before plugging in, ensure the voltage and frequency of the AC power meet the requirement (100-240VAC, 50/60Hz).
- Make sure the power is off, before connecting to power supply.
- Do not touch the power switch and power cord with wet hands.
- Do not unplug the power cord before the instrument is powered off.
- Disconnect from power when cleaning the instrument.
- Disconnect from power when replacing the fuse.

- Switch off when the instrument is not in use.
- If there is a power failure during operation, run the complete experiment again after power is restored.

1.4 Electromagnetic Compatibility

- The manufacturer provides electromagnetic interference precautions to customers and users.
- The operator must ensure the installation environment of the instrument complies with the electromagnetic interference precautions.
- This instrument has been tested and complies with the standard EN 61236 (group 1, class B).
- It is recommended to evaluate the electromagnetic interference before installing the instrument.
- Do not use this instrument in close proximity to sources of strong electromagnetic radiation. Strong electromagnetic radiation may interfere with the proper operation of the instrument.

Chapter 2: Overview

This instrument and PCR reagents run fluorescent polymerase chain reaction (PCR). It provides quantitative and qualitative results on the RNA/DNA samples, for pathogens and human gene experiments.

Instrument features:

1. Latest semiconductor thermoelectric cooling technology offers reliable performance.
2. High resolution and smooth operation with 10.1 inches LCD capacitive touch screen.
3. Large data storage, supports > 200,000 experiment records.
4. Optimized for rapid detection – completes PCR test in less than 30 minutes.

5. USB 2.0 port for flash drive storage and Wi-Fi enabled.
6. Friendly user experience on Android-based system.
7. Throughput: 16 x 0.2 mL (two 8-strip tube), double 8 wells.
Reaction volume: 20-100 µL.
8. Real time display of data during experiment run.
9. Offers analysis and results, right after experiment runs.

Chapter 3: Technical Specifications

3.1 Name and Model

The real-time fluorescence quantitative PCR instrument, produced by Wuxi Opulen Technology Co., Ltd. (name of the manufacturer). Model number: OP-qPCR1600.

3.2 Application

The instrument, with PCR reagents, is used for detecting gene expression. Its rapid amplification process makes it especially suitable for POCT.

3.3 Functionality

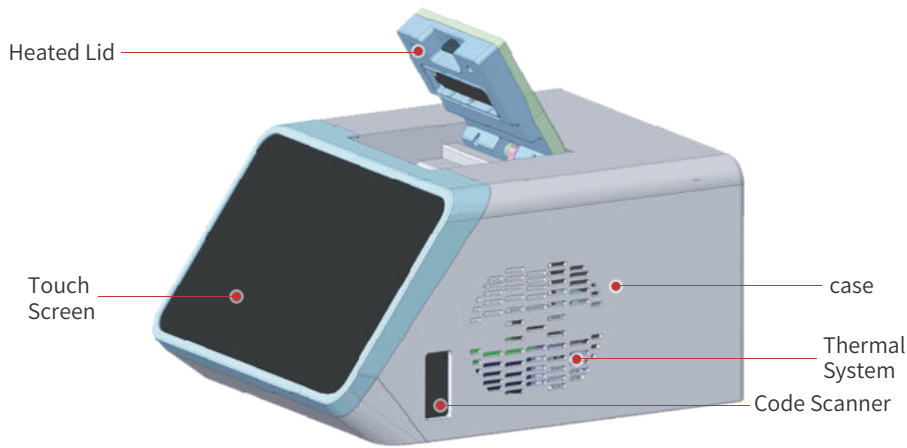
The instrument shall be used with compatible reagents. The thermal module creates environment for RNA reverse transcription and amplification, including denaturation, annealing, and extension cycles. The photoelectric module reads fluorescent signal generated during the amplification process in real time. The system simultaneously produces analysis, on the target gene sequence in the sample.

3.4 Technical Specifications

Specification	Standards
Sample Throughput	16 x 0.2 ml (two 8-strip tube), double 8 wells Sample volume: 20-100 μ L
Reaction Volume	20-100 μ L
Fluorescent Probes	F1: FAM、SYBR Green I
	F2: HEX、VIC、JOE
	F3: ROX、TEXAS RED
	F4: Cy5
Metal Thermal Module	10-100°C
Temperature Uniformity	$\leq 1^{\circ}\text{C}$
Thermal Control Precision	$\leq 0.5^{\circ}\text{C}$
Average Heating Rate	$\geq 4.5^{\circ}\text{C/s}$
Max. Heating Rate	$\geq 6.5^{\circ}\text{C/s}$
Average Cooling Rate	$\geq 3.2^{\circ}\text{C/s}$
Max. Cooling Rate	$\geq 5.1^{\circ}\text{C/s}$
Heated Lid Temperature Range	30-120°C
Fluorescence Variation	$\text{CV} \leq 3\%$
Test Result Variation	$\text{CV} \leq 3\%$
Test Linearity	regression coefficients $r \geq 0.990$
Fluorescence Linearity	regression coefficients $r \geq 0.990$
Display	10.1 inches LCD touch screen
Power Supply	100-240V, AC 50/60Hz, Max 800VA
Ports	USB, RS-232 serial port, ethernet
Dimension	300mm \times 370mm \times 190mm
Weight	10.4Kg

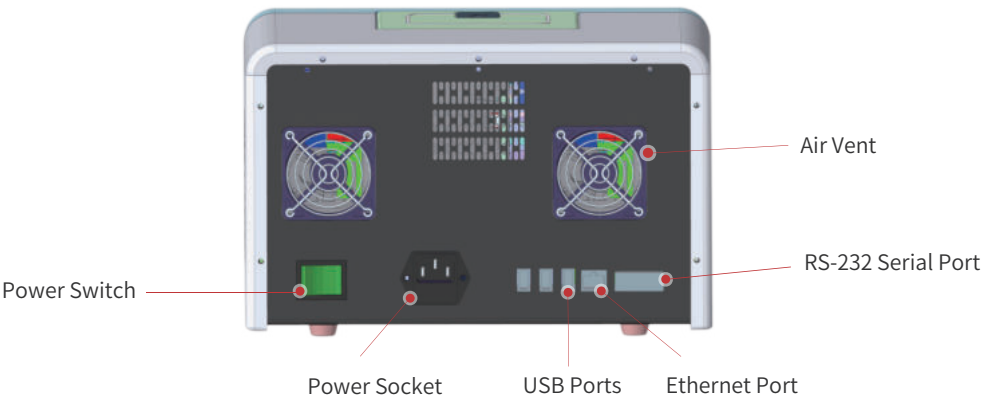
3.5 Modules

The instrument is consisted of control system, thermal system, photoelectric system, heated lid module, case module, and software system, etc.



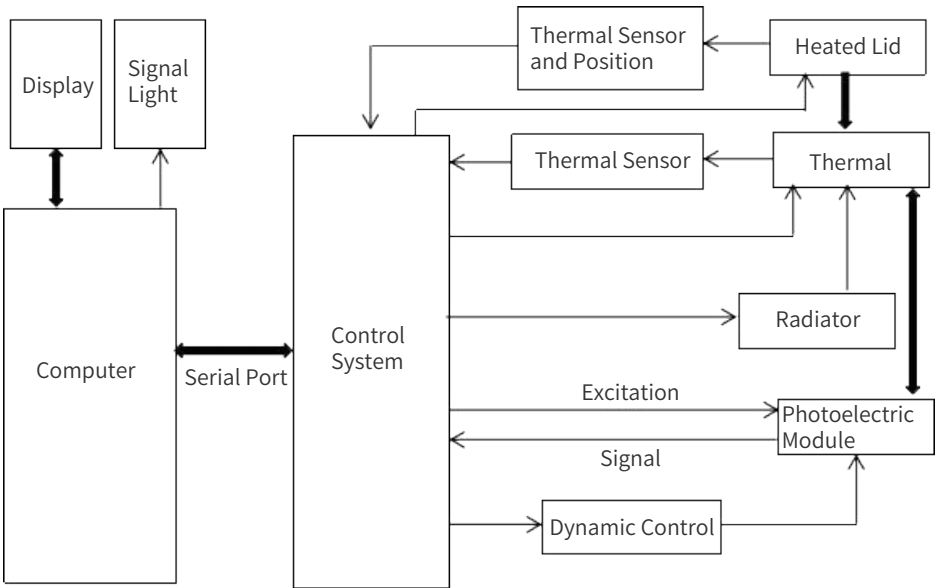
(Figure 3.5.1)

On back of the instrument, there are USB ports x 3, ethernet port x 1, RS-232 serial port x 1, a power switch, and a power socket.



(Figure 3.5.2)

System Schema



(Figure 3.5.3)

Main Functional Modules	Module Description
Heated Lid	Make sure the temperature above test tubes is higher than the temperature of the test tubes, to prevent water condensation on the cover.
Thermal Module	Controls amplification temperature. It is consisted of a heating module, a cooling module, a thermal sensor, and a radiator, etc. Tubes are heated with heating module and cooled with air cooling.
Photoelectric Module	Collects data readings during the experiment.
Control Module	Controls all the heating and cooling modules, optical modules, thermal sensors, and user interface, etc.
Touch Screen	Human interaction interface that comminates with the computer.
Scanner	Used to scan barcodes on tubes.

3.6 Software

1) Name: Real-Time Fluorescence Quantitative PCR Software

2) Model: OP-qPCR1600

3) Release version: Ver1

4) Version naming: VerX.Y.yyyymmdd (all integers)

X: major software update, such as new modules, architecture change, major upgrades;

Y: minor software update: minor function change;

yyymmdd: Bug fixes or minor changes.

5) Software Performance

- Page load < 2 seconds
- Authentication: unauthorized user access prompts “Login Failed” or “Please check whether the ID and password you entered are correct” .
- Reliability: When the system is stuck, restart the system and the system will be restored.
- Compatibility: The system runs on ARM architecture Android System (version number: 5.1.1).
- Portability: The software can't be installed on other devices.
- Database backup and restore: Database is backed up automatically. To restore data, import the database backup file from flash drive to the database.
- User Interface: menu, windows, function keys.
- Restrictions: Instrument may only be used by authorized personnel.
- System Error Prompt: message prompts when a user error occurs.
- Software version change notification: The system displays the model and version number on the login screen. The version number updates with software updates.
- System busy, performance issues, system overload, and services down may cause system errors or data loss.
- System Incidents:
 1. Hard drive damage may cause data loss.
 2. Deleting system authorization files may remove access to the system.
- LOG files: includes system error logs and service logs.

3.7 Classification

Following Regulation (EU) 2017/746, this instrument is classified as Class A diagnostic medical devices.

3.8 Contraindications

None.

3.9 Service Life

- Service Life: 5 years (excluding human damage).
- The production date is shown on the nameplate of the instrument.
- After the service life, the instrument and accessories should be disposed following local regulations.

3.10 Accessories

See the instrument packing slip for detail.

Chapter 4: Installation

4.1 Transportation and Storage

This is a delicate instrument. Packaging is not required when moving short distance indoors. However, original packaging is required, when moving by vehicles. When the instrument is shipped, the packaging must be moisture-proof, shock-proof, and handled with care. Keep the instrument's right side up. Protect it from impact, rain, or direct sun light. Shipping temperature: -20°C ~ 55°C, humidity: ≤90%, pressure: 75kPa ~ 106kPa.

Storage Condition: -20 ~ 55 °C, humidity: ≤90%, pressure 75kPa ~ 106kPa, away from corrosive substances and in well-ventilated space.

4.2 Operation Environment Requirements

4.2.1 Operation Site

- The instrument should be used indoors only. The workbench must be level and stable.
- The instrument should be installed in a place with low humidity, free of dust, and away from water (pools, water pipes, etc.). The room should be well ventilated and free from corrosive gases or strong magnetic fields. Never place the instrument in a humid or dusty space.
- The openings on the instrument are for ventilation, to avoid overheating. Do not block or cover the air vent. The space between the air vent and adjacent objects, should be greater than 30cm. When two instruments are installed next to each other, distance between them should be greater than 50cm.
- Heat could affect performance of the instrument or cause malfunction. Do not use the instrument under direct sunlight and strong light sources, so as not to affect the fluorescence detection. Keep away from heaters, stoves, and all other heat sources.



Do not cover the air vent when the instrument is running.

4.2.2 Operation Environment

- Power Supply: 100 - 240VAC, 50/60Hz
- Temperature: 15°C ~ 30°C
- Relative humidity: 10% ~ 80%
- Atmospheric pressure: 86kPa ~ 106kPa
- Indoor use only, Altitude < 2000m
- Keep away from mechanical vibration and shock
- No strong electromagnetic field interference
- Properly grounded electric receptacle

4.3 Unpacking

The instrument is packed in carboard box, filled with shock-absorbing material. When unpacking, make sure the package is not damaged during shipping and all accessories are in place - which confirms that transportation has not caused damage.

Packing slip:

Name	Specification and Model	Quantity
PCR instrument	OP-qPCR1600	1
Power cord	EU standard, 250V, 10A	1
Fuse	Φ5×20mm - F10AL250V	2
Dust cover	-	1
Lint-free wipe	-	1
Air blow	-	1
User Guide, Certificate of Quality, Warranty Card, Packing Slip	-	1 for each



In case the instrument is damaged from shipping, do not use it and contact your sales representative.

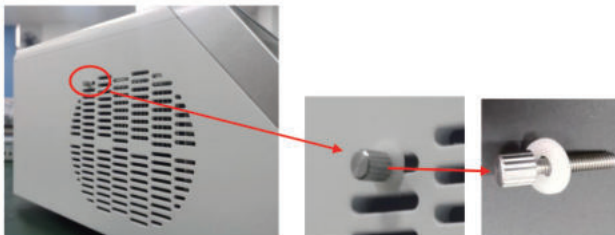
4.4 Removing the transport lock



Following unpacking, the shipping lock must be removed before powering on the instrument.

The transport lock locks the detection head, to keep it from collision during transportation, as shown in Figure 4.4.1. Remove the transport lock following instructions:

- ① Make sure the instrument is powered off.
- ② Turn the screw counterclockwise until it is removed.
- ③ Keep the locking screws for future use.



(Figure 4.4.1)

4.5 Installation

- Unwrap the instrument and remove the transportation locks. Follow section 4.2.1 to install the instrument.
- Connect the instrument to power socket with the power cord provided.
- Turn the power switch at the back of the instrument to "—" position. The instrument is powered on, the program starts to run, and the screen lights up.
- To turn off the instrument, turn the power switch at the back of the instrument to the "○" position, and then unplug the power cord.

4.6 Printer (Optional)

The printer is an auxiliary device. The instrument can print out test results by connecting to matching printer models. Connect printer as shown in Figure 4.6.1: connect RS-232 cable from the instrument to the printer, then connect power cord of the printer to complete printer installation.



(Figure 4.6.1)



Only matching printer models function properly with the instrument.

4.7 Security



Follow this recommendation to avoid misuse, malwares, or cyber-attack. Set screen lock (pattern or pin). Contact sales representative for details.



Do not quit or uninstall pre-installed security software. Do not use untrusted flash drive and Wi-Fi connections.

4.8 Connect to LIS

Connect the instrument to LIS through Wi-Fi or ethernet cable, to upload result data to the LIS. Contact sales for more information.



4.9 Update

System Update Steps:

- ① Turn on the instrument and insert flash drive with the installation package into the USB Port on the device (figure 4.9.1). Make sure the installation file name ends with ".apk". The flash drive format is FAT32.



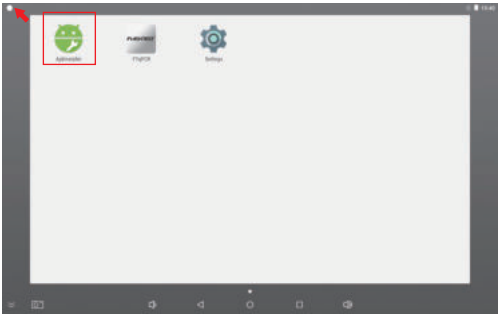
(Figure 4.9.1)

- ② Long press the  button at the bottom of the screen for 5 seconds, to go to the Android home screen. Tap  button to bring up the Android System Screen. As shown in figure 4.9.2.





(Figure 4.9.2)

③ Check if there is a white dot on the top left corner of the screen, which indicates the flash drive is mounted successfully. Then press "Apk Installer", as shown in Figure 4.9.3.



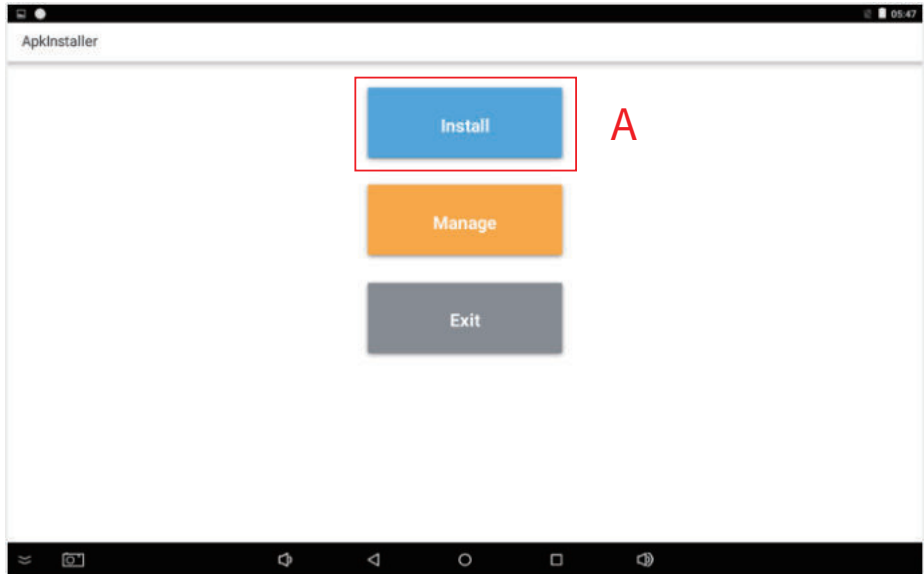
(Figure 4.9.3)

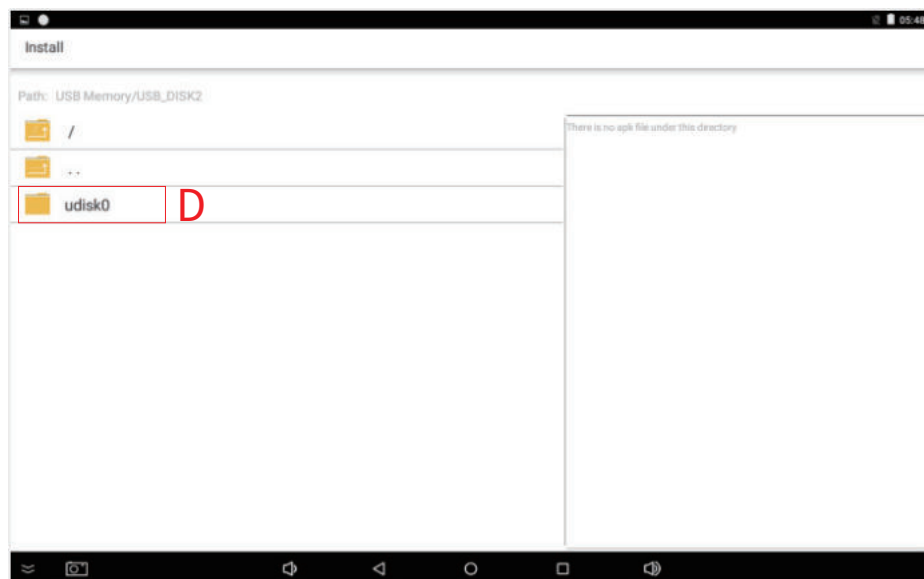
④ On the Apk installation program, press  /  to toggle password visibility during login. Enter password "opulentec2021", then press "LOGIN", as shown in Figure 4.9.4.

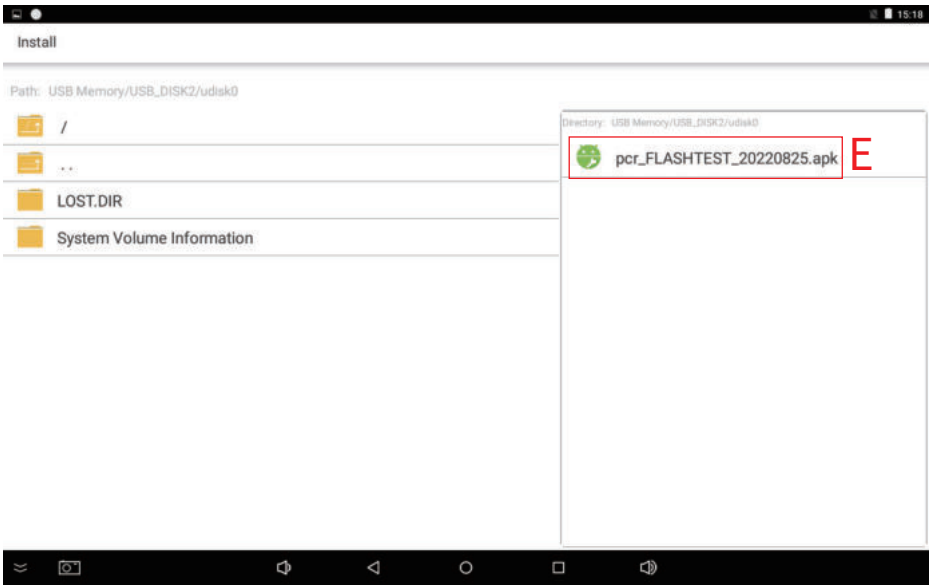


(Figure 4.9.4)

⑤ Follow steps A – E to install the PCR system, as shown in Figure 4.9.5.

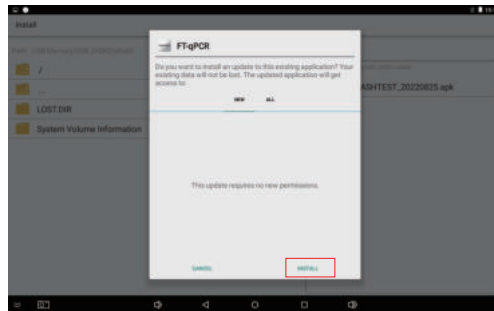






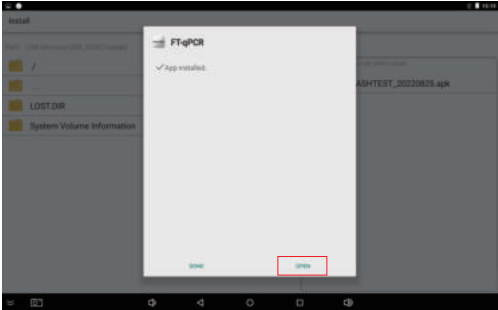
(Figure 4.9.5)

⑥ Press "INSTALL" to start installation, as shown in Figure 4.9.6.



(Figure 4.9.6)

⑦ When installation is complete, press "OPEN", as shown in Figure 4.9.7.



(Figure 4.9.7)

⑧ On the PCR system screen, verify the system version number on the bottom right is correct, as shown in Figure 4.9.8.



(Figure 4.9.8)

⑨ Remove the flash drive from the device, when installation is complete.

Chapter 5: Operation Configurations

5.1 Check Before Start

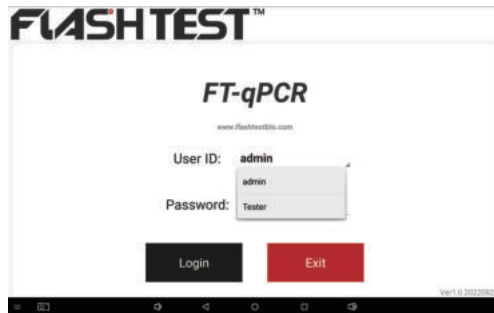
Before switching on the instrument, check the following:

- The power supply meets requirements.
- Power cord is properly plugged into the power outlet.
- The working environment meets standard.

5.2 Start-up Interface

When the instrument is turned on, the login page shows up. Use an administrator or user account to log in (user accounts are created in the user management setting). Default admin password is 12345.

Press "Login" to enter. Press "Exit" to quit, as shown in Figure 5.2.1:



(Figure 5.2.1)

5.3 Software Interfaces

5.3.1 Main Control:

Main Control shown in Figure 5.3.1.1:



(Figure 5.3.1.1)

There are four tabs:



Menu: set system parameters



Main Control: experiment run interface



Analysis: amplification curve and Ct value



History: view history results

5.3.2 Menu

5.3.2.1 Admin Account Menu Options

Log in as Admin, there are three options: System Setting, User Management, and Program Setting.



(Figure 5.3.2.1.1)

System Setting:

The screenshot shows the 'System Setting' screen of the FLASHTEST application. At the top, there are navigation icons for Home, Main Control, Analysis, History, and a Save button. The settings are organized into several sections: 'Software Version' (ver1.0.20220628), 'Used Time' (0:00:00), 'URL' (http://172.16.16.120:8080), 'Device ID' (22090001020), and 'Hospital Name'. Below these are three toggle switches: 'Upload Result' (Yes/No), 'Print or not' (Yes/No), and 'Code Scanner' (Turn On/Turn Off). Each toggle switch has a blue dot indicating its current state. At the bottom right, there is a 'Save' button.

(Figure 5.3.2.1.2)

Software version: the major version of the software

Full version: the version of the software

Used time: accumulated use time of the instrument

URL: the instrument is connected to the URL address

Device ID.: instrument ID number

Hospital Name: name of the hospital (editable)

Upload Results: Upload experiment results to the web address (URL)

Yes: turn on result uploading

No: turn off result uploading

Print or not: Whether print test results through connected external printer

Yes: print result

No: Do not print result

Code Scanner: code scanner settings

Turn on: turn LED flashlight on

Turn off: turn LED flashlight off

Laser on: turn on laser barcode scanner

Laser off: turn off laser barcode scanner

Save: save configuration

User Management: Manage user accounts. Create, edit, and delete regular user accounts (admin account cannot be deleted):



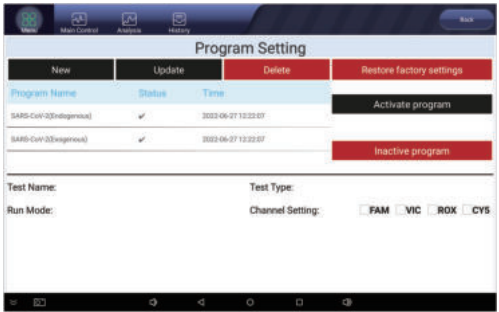
(Figure 5.3.2.1.3)

Add: create new user account

Update: select user account to be updated, then press "update"

Delete: select user account to be deleted, then press "delete"

Program Setting: Create and update experiment configurations



(Figure 5.3.2.1.4)

Select a program, program details are shown:



(Figure 5.3.2.1.5)

New: Create a new program

Update: Modify selected program

Delete: delete selected program

Factory Reset: delete all programs, and reset programs settings to factory defaults

Activate program: activate selected program

Inactive program: deactivate selected program

Test Name: test name of selected program

Test Type: test type of selected program

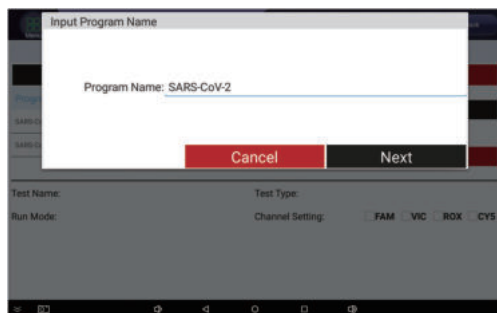
Run Mode: run mode of selected program

Channel Settings: active florescence channels of selected program

The bottom section shows the temperature and time settings of each reaction stage.

When creating a new program, there is an additional step of setting the program name, as shown below:

- ① On Program Setting page, press "New". Enter a program name for the new program, which cannot be the same as any existing program names:

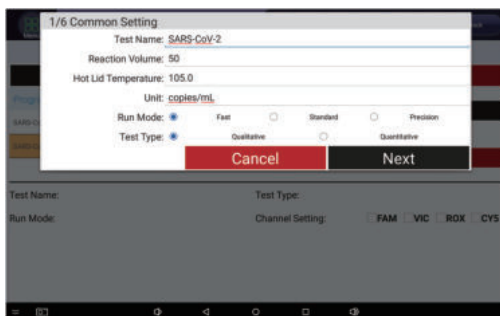


(Figure 5.3.2.1.6)

Cancel: cancel new program creation

Next: proceed to the next step

② Common Setting page



(Figure 5.3.2.1.7)

Test Name: test name of the program

Reaction Volume: reaction volume of a single PCR tube

Heated Lid Temperature: heating temperature of the heated lid. Please set the temperature following experiment specifications.

Unit: unit of quantitative detection concentration

Run Mode: select run mode:

Fast: for reagent with high temperature tolerance

Standard: for reagent with standard temperature tolerance

Precision: for reagent with low temperature tolerance

temperature transition rate: Fast > Standard > Precision

thermal control precision: Precision > Standard > Fast

Test Type: select qualitative or quantitative detection mode

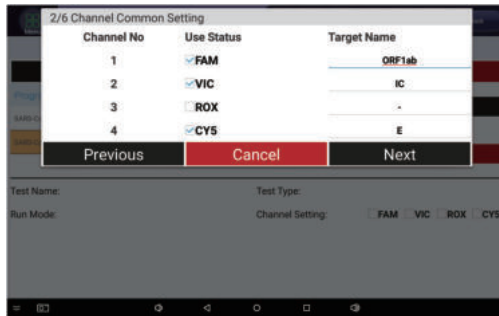
Qualitative: test for Ct value

Quantitative: test for Cn value - use Cn and Ct of internal standard to plot standard curve, then use the standard curve to derive Cn, from Ct.

Cancel: cancel program setting

Next: proceed to the next step

③ Channel Common Setting



(Figure 5.3.2.1.8)

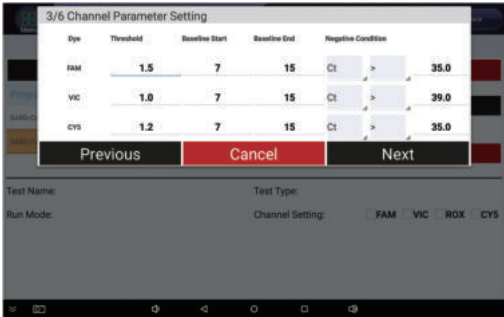
Select fluorescent channels and set target name for each channel.

Previous: return to previous setting

Cancel: cancel program setting

Next: proceed to the next step

④ When test type is qualitative



(Figure 5.3.2.1.9)

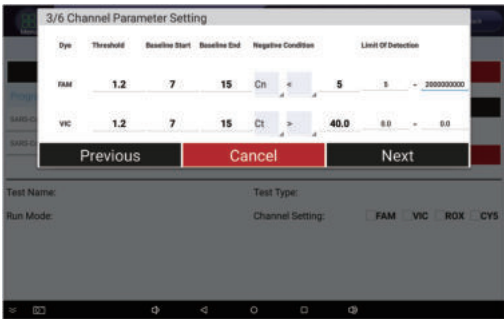
Set florescence channel parameters, for selected dyes.

Previous: return to previous setting

Cancel: cancel program setting

Next: proceed to the next step

When test type is **quantitative**:



(Figure 5.3.2.1.10)

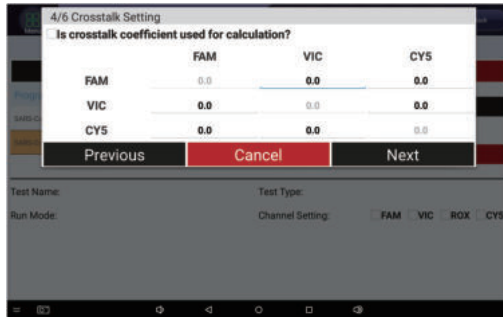
Set florescence channel parameters, for selected dyes.

Previous: return to previous setting

Cancel: cancel program setting

Next: proceed to the next step

⑤ Crosstalk Setting



4/6 Crosstalk Setting

Is crosstalk coefficient used for calculation?

	FAM	VIC	CY5
FAM	0.0	0.0	0.0
VIC	0.0	0.0	0.0
CY5	0.0	0.0	0.0

Previous Cancel Next

Test Name: Test Type:
Run Mode: Channel Setting: FAM VIC ROX CY5

(Figure 5.3.2.1.11)


Crosstalk coefficient setting: Users can refer to the instructions provided by the reagent kit manufacturer and input the appropriate crosstalk coefficient value in the current interface. Crosstalk means in a multiplex experiment, due to the slight overlap of the excitation light wavelength generated by dyes or probes, the fluorescence signals between channels marginally interfere with each other. The degree of interference between different reagents could be different. Set the crosstalk coefficient between channels to eliminate multichannel interference.

Previous: return to previous setting

Cancel: cancel program setting

Next: proceed to the next step

⑥ Program Setting:



5/6 Program Setting

Cycle	Mark	Temperature	Hold Time
1	◇	90.0	180
2	◇	94.0	30
3	◇	94.0	2
4	●	58.0	12

Previous Cancel Next

Test Name: Test Type:
Run Mode: Channel Setting: FAM VIC ROX CY5

(Figure 5.3.2.1.12)

Add Holding Stage: Add a holding stage, marked as "◇"

Add Cycling Stage: Set cycle loop number

Add Standard Step: add a standard step that does not collect fluorescent signal, marked as "○"

Add Acquisition Step: add a step that collects fluorescent signal data, marked as "●"

Update: edit parameters for selected program

Delete: delete selected program

Previous: return to previous setting

Cancel: cancel program setting

Next: proceed to the next step

Example: experiment instruction of the sample reagent is as follows:

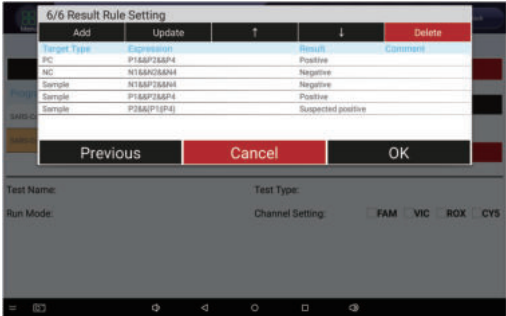
Stage	Temperature	Time	Cycle Number	Detect Fluorescent Signal?
1	50°C	3mins	1cycle	no
2	94°C	30secs	1cycle	no
3	94°C	2secs	40cycle	no
	58°C	12secs		yes

program setting of the sample reagent is as follows:

Cycle	Mark	Temperature	Hold Time
	◇	50.0	180
	◇	94.0	30
40			
	○	94.0	2
	●	58.0	12

(Figure 5.3.2.1.13)

⑦ After pressing "Next" on the Program Setting Page, to go to Result Rule Setting page



(Figure 5.3.2.1.14)

Add: add a result rule

Update: update selected result rule

↑ : Move selected rule one step up

↓ : Move selected rule one step down

(The analysis engine applies rules from top to bottom.)

Delete: delete selected rule

Previous: return to previous setting

Cancel: cancel program setting

OK: All settings take effect

Pressing "Add" or "Update" to edit the expression.



(Figure 5.3.2.1.15)

Expression shows the current expression

Target Type: select target type from drop down menu

Result Type: select result type from drop down menu

Comment: edit comment

Clear: clear expression window

Reset: reset the express back to before the modification

Cancel: cancel editing and close the popup window

OK: save changes

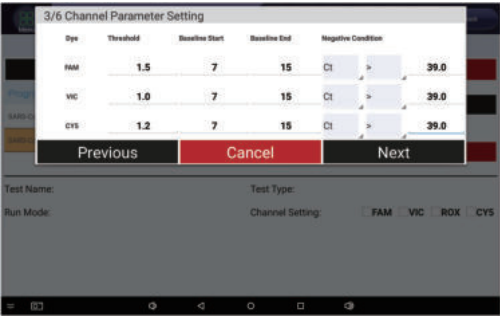
Button Explanation:

Button	Value	Button	Value	Button	Value	Button	Value
T1	FAM channel Ct	C1	FAM channel concentration	P1	FAM channel positive	N1	FAM channel negative
T2	VIC channel Ct	C2	VIC channel concentration	P2	VIC channel positive	N2	VIC channel negative
T3	ROX channel Ct	C3	ROX channel concentration	P3	ROX channel positive	N3	ROX channel negative
T4	CY5 channel Ct	C4	CY5 channel concentration	P4	CY5 channel positive	N4	CY5 channel negative
E+	Exponential 10^A	&&	Satisfy both conditions		Satisfy at least one condition	Del	Delete

Example: the control samples and test sample results are as follows: The test runs for 40 cycles.

Sample Type	Channel			Result Reading
	FAM	VIC	CY5	
Positive Control	CT≤39	CT≤39	CT≤39	positive
Negative Control	No Ct	No Ct	No Ct	negative
Sample	No Ct	CT≤39	No Ct	negative
	CT≤39	CT≤39	CT≤39	positive
	No Ct	CT≤39	CT≤39	Suspected positive, recommend retest.
	CT≤39	CT≤39	No Ct	

Based on above rules, first set the negative threshold to 39, then edit the channel parameters, as shown below:



(Figure 5.3.2.1.16)

Set result rules for the program as follows:

Target Type	Expression	Result	Comment
PC	P1&&P2&&P4	Positive	
NC	N1&&N2&&N4	Negative	
Sample	N1&&P2&&N4	Negative	
Sample	P1&&P2&&P4	Positive	
Sample	P2&&(P1 P4)	Suspected positive	

(Figure5.3.2.1.17)

Quick Import / Export of Program Settings

① Export Program Settings: On Program Setting page, long press the program setting to be exported for 2 seconds, below popup window shows:



(Figure 5.3.2.1.18)

Cancel: close this window

Export: Export selected program setting as a QR code and save to a mounted flash drive. Tap "Export" and the instrument shows "Export Succeeded!", when the QR code is saved successfully. Path of exported QR code: find QPCR folder in the flash drive root folder.

Exported file name: same as the program name.

Exported file type: .png

② Import Program Settings: Take the program setting QR code image and scan with the QR code laser scanner on right side of the instrument. It automatically detects and imports the program setting to the instrument. When import is successful, prompt "The program has been written!" shows.

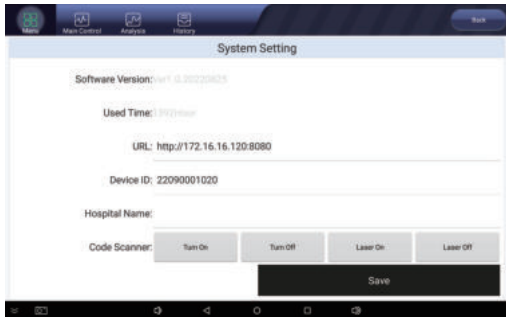
5.3.2.2 Regular User Account

After logging in as a regular user, System Setting and User Management shows on the Menu page.



(Figure 5.3.2.2.1)

System Setting: System Setting as shown in 5.3.2.2.2



(Figure 5.3.2.2.2)

Software Version: the major version of the software

Full version: the version of the software

Used Time: accumulated use time of the instrument

URL: the instrument is connected to the URL address

Device ID.: instrument ID number

Hospital Name: name of the hospital (editable)

Code Scanner: code scanner settings

Turn on: turn LED flashlight on

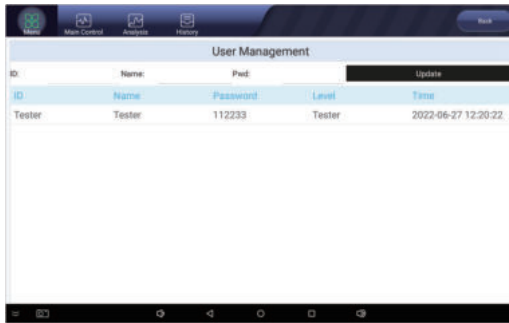
Turn off: turn LED flashlight off

Laser on: turn on laser barcode scanner

Laser off: turn off laser barcode scanner

Save: save configuration

User Management: Update logged in user account. Create, edit, and delete regular user accounts (admin account cannot be deleted):



(Figure 5.3.2.2.3)

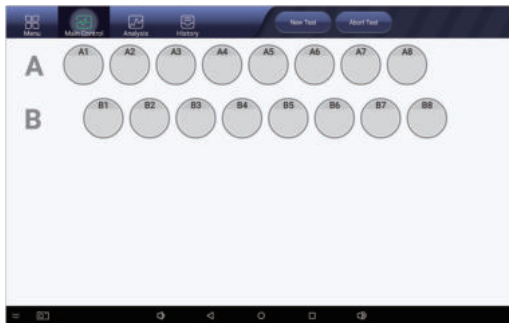
Update: select user account to be updated, then press "update"

5.3.3 Main Control

On the main control page, select test wells to enter sample information. There are 16 wells:

Row A: A1~A8

Row B: B1~B8



(Figure 5.3.3.1)

New Test

New Test: start a new test

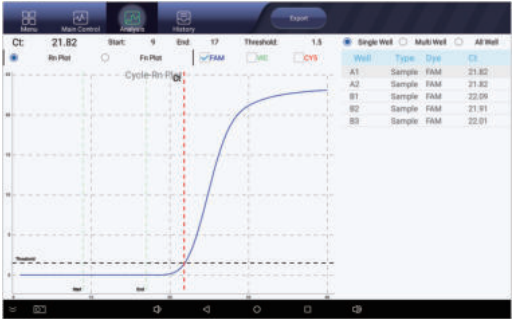
Abort Test

Abort Test: abort test while running

5.3.4 Analysis

5.3.4.1 Qualitative Analysis

Plot amplification curve in real time, while running. Plot the Ct when the run is complete.



(Figure 5.3.4.1.1)

Check boxes to show selected amplification curve.



(Figure 5.3.4.1.2)

Rn curve: fitted amplification curve, shown when the run is complete

Fn curve: actual amplification curve, shown in real time during the run

Single well: view amplification curve of a single well

Multi well: view amplification curves of multiple wells

All Well: view amplification curves of all wells

5.3.4.2 Quantitative Analysis

Quantitative analysis has the Standard Curve plot option.



(Figure 5.3.4.2)

Standard Curve: when quantitative test is complete, the analytical engine uses log10 of the standard control and Ct value of the sample as inputs, to plot a linear standard. The Cn value is then derived from Ct value and the standard curve.

R2: linear coefficient, must be greater than 0.990

Formula: function of standard curve

Efficiency: efficiency

5.3.5 History

View, upload, export(print), and re-analysis of history results. In addition to all qualitative test values, the quantitative test has channel concentration value.

History page of qualitative test:

Well	Sample	Test Type	Result	Channel	Concentration	Efficiency	Result	Channel	Concentration	Efficiency
A1	20220601-0041	SWIS-CurV-2	Qualitative	NoCt	29.28	-	E	Qualitative	29.28	-
A2	20220601-0041	SWIS-CurV-2	Qualitative	NoCt	28.91	-	E	Qualitative	28.91	-
A3	20220601-0041	SWIS-CurV-2	Qualitative	NoCt	27.21	-	E	Qualitative	27.21	-
A4	20220601-0041	SWIS-CurV-2	Qualitative	NoCt	27.31	-	E	Qualitative	27.31	-
A5	20220601-0041	SWIS-CurV-2	Qualitative	NoCt	25.22	-	E	Qualitative	25.22	-
A6	20220601-0041	SWIS-CurV-2	Qualitative	NoCt	29.09	-	E	Qualitative	29.09	-

(Figure 5.3.5.1)

History page of quantitative test:



Serial Number	Test Name	IS	IC	WC	IS	Result
Serial	Test Type	IS	IC	IS	IS	Comment
Sample ID	Concentration	Concentration	Concentration	Concentration	Concentration	Pincode Value
admin		100.0	0.0	-	-	2022-06-23 14:03:09
20220623-0001	Standard	HBV	IC	-	-	
A0	Quantitative	29.87	34.76	-	-	
admin		1000.0	0.0	-	-	2022-06-23 14:03:09
20220623-0001	Standard	HBV	IC	-	-	
A4	Quantitative	29.67	31.56	-	-	
admin		10000.0	0.0	-	-	2022-06-23 14:03:09
20220623-0001	Standard	HBV	IC	-	-	
A5	Quantitative	23.44	28.13	-	-	
admin		100000.0	0.0	-	-	2022-06-23 14:03:09
20220623-0001	HBV	HBV	IC	-	-	
A6	Quantitative	29.93	25.04	-	-	
admin		1.029E3 T	-	-	-	2022-06-23 14:03:09
20220623-0001	HBV	HBV	IC	-	-	
A7	Quantitative	32.84	37.7	-	-	
admin		8.62E1 T	-	-	-	2022-06-23 14:03:09
20220623-0001	HBV	HBV	IC	-	-	
A8	Quantitative	Nu3	37.56	-	-	
admin		<5.0	-	-	-	2022-06-23 14:03:09

(Figure 5.3.5.2)


Filter

Filter: Filter test results

Send Report

Send Report: Send selected result to specified URL address

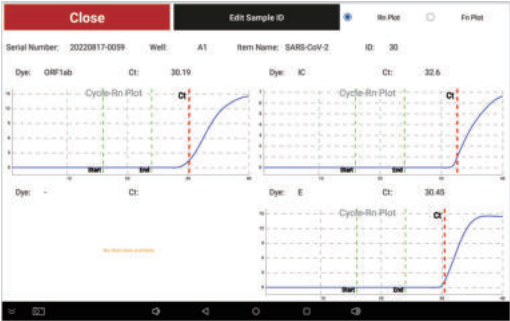
Export

Export: Export selected result data to a mounted flash drive. Save to the QPCR folder under the flash drive root directory. Results are exported as csv format. If print function is enabled in system setting, after instrument restart, this button will be , which prints selected results.

Reanalysis




Reanalysis: show test results under analysis tab.

Long press a single test result, its amplification curves show on the screen. Tap "Close" to close this view, Press "Edit Sample ID" to edit sample ID.



(Figure 5.3.5.7)

5.3.6 Heated Lid Status Light

Instrument Status	Light Color	Light State	Illustration
Boot up completed	Blue	Steady	
During test run	Green	Flashing	
Test run completed	Green	Steady	

Chapter 6: Test Well Setting

6.1 Qualitative Test Setting

① Tap "New Test" on Main Control



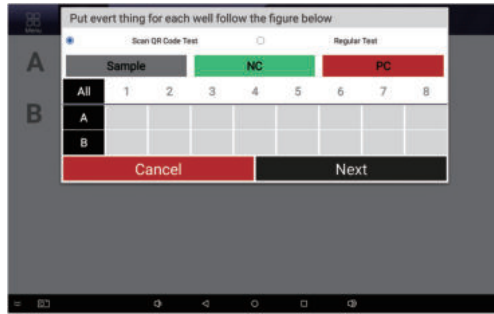
(Figure 6.1.1)

② If there are multiple active programs, select a program before starting test. Tap "Next" to proceed.



(Figure 6.1.2)

③ Set well information based on experiment specifications

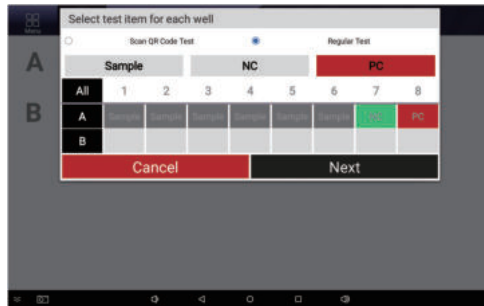


(Figure 6.1.3)

Scan QR Code Test: use scanner to input sample information

Regular Test: Manually enter the sample type and information to perform the detection. Operations illustrated below use the Regular Test mode.

④ Put PCR tubes into the wells. Assign sample type accordingly, for each well.



(Figure 6.1.4)

Sample

Sample: turns to dark grey when selected

NC

NC: negative control, turns to green when selected

PC

PC: positive control, turns to red when selected

All

ALL: select all wells

A

A: select all wells in row A

B

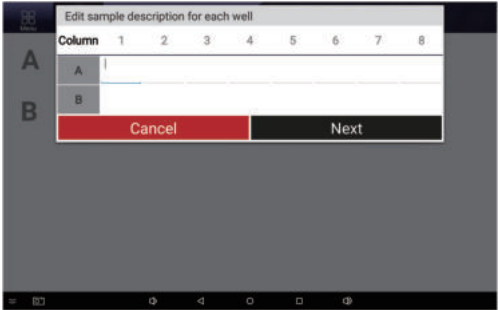
B: select all wells in row B

- Cancel

Cancel: cancel well settings
- Next

Next: confirm wells settings and proceed to next step

⑤ Enter description for each well. Description can be input by a code scanner or by hand.



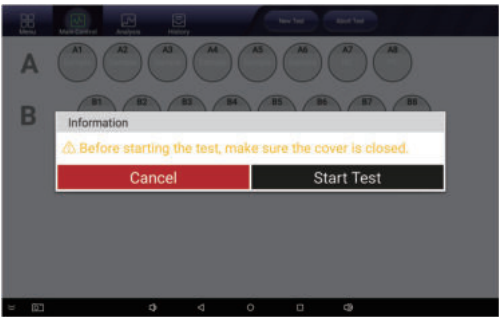
(Figure 6.1.15)

- Cancel

Cancel: cancel well settings
- Next

Next: confirm wells settings and proceed to next step

⑥ Make sure the heated lid is properly closed, before start a test. Do not open the heated lid during a test.



(Figure 6.1.16)

- Cancel

Cancel: cancel well settings
- Start Test

Start Test: start test



(Figure 6.3.1)

② After completing preheat, Main Control shows test timer and temperature and time of each stage.



(Figure 6.3.2)

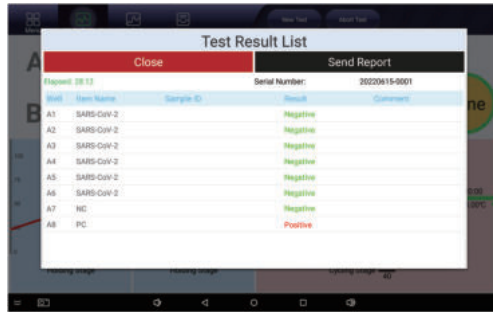
③ Realtime amplification plot is found under the analysis tab. Refer to 5.3.4 for details of Analysis.



(Figure 6.3.3)

6.4 Test Results

- ① When test is completed, test results and test time are found in the Test Result List.



(Figure 6.4.1)

Close

Close: close test result list

Send Report

Send Report: send test result list to specified URL address.

- ② Once the test is complete, test results are generated under History. Refer to 5.3.5 for details of History.

Serial Number	Item Name	Item Type	Item	Item	Item	Item	Item	Result
Serial	Test Name	Test Type	Test	Test	Test	Test	Test	Test
20220601-0041	SARS-CoV-2	Qualitative	IC	IC	IC	IC	IC	Negative
A1	Qualitative	NoCI	29.28	-	-	-	-	-
admin	41	-	-	-	-	-	-	2022-06-02 11:09:00
20220601-0041	SARS-CoV-2	Qualitative	IC	IC	IC	IC	IC	Negative
A2	Qualitative	NoCI	28.91	-	-	-	-	-
admin	41	-	-	-	-	-	-	2022-06-02 11:09:00
20220601-0041	SARS-CoV-2	Qualitative	IC	IC	IC	IC	IC	Negative
A3	Qualitative	NoCI	27.21	-	-	-	-	-
admin	41	-	-	-	-	-	-	2022-06-02 11:09:00
20220601-0041	SARS-CoV-2	Qualitative	IC	IC	IC	IC	IC	Negative
A4	Qualitative	NoCI	27.31	-	-	-	-	-
admin	41	-	-	-	-	-	-	2022-06-02 11:09:00
20220601-0041	SARS-CoV-2	Qualitative	IC	IC	IC	IC	IC	Negative
A5	Qualitative	NoCI	25.23	-	-	-	-	-
admin	41	-	-	-	-	-	-	2022-06-02 11:09:00
20220601-0041	SARS-CoV-2	Qualitative	IC	IC	IC	IC	IC	Negative
A6	Qualitative	NoCI	29.99	-	-	-	-	-
admin	41	-	-	-	-	-	-	2022-06-02 11:09:00

(Figure 6.4.2)

Chapter 7: RT-PCR Test Demo

Test procedure:

① Instrument setup: turn on the instrument and enter Main Control. The heated lid status light is steady blue.



(Figure 7.1)

② Reagent preparation, from left to right:

Purple cap: reverse transcriptase

Green cap: RT-PCR master mix

Blue cap: negative control

Red cap: positive control



(Figure 7.2)

③ Reagent premix:

- a. Open the large cap of the reverse transcriptase (purple).
- b. Open the small cap of the RT-PCR master mix (green).
- c. Squeeze all RT-PCR master mix (green) into the reverse transcriptase tube (purple).
- d. Fasten the cap of the reverse transcriptase tube (purple). Mixing by inverting the tube 3-5 times. Avoid bubbles.



(Figure 7.3)

④ Waste disposal:

4.1 Place the small cap of the RT-PCR master mix (green).

4.2 Open the large cap of the RT-PCR master mix (green).

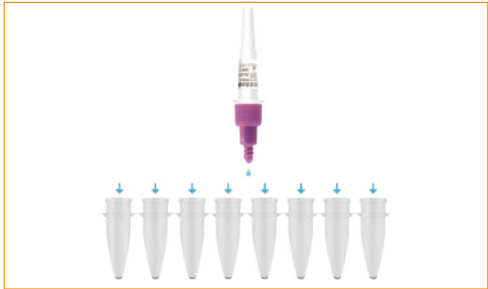
This tube is used as the waste tube.

4.3 Discard the first drop of the reagent mix (purple), into the waste tube (green).



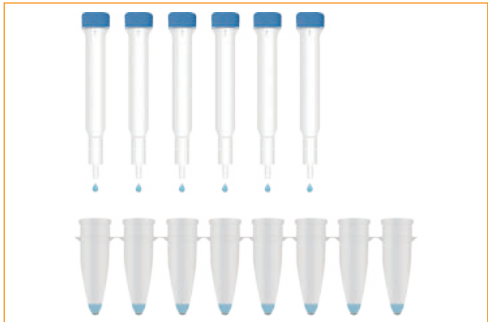
(Figure 7.4)

⑤ Add reagent: Add one drop of reagent mix (purple) each of the 8-strip PCR tubes.



(Figure 7.5)

⑥ Add Sample: Discard the first two drops of the sample into the waste tube. Add one drop of sample into the corresponding PCR tube.



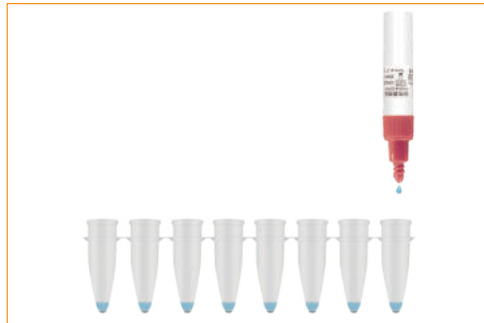
(Figure 7.6)

⑦ Add negative control: add one drop of negative control into the designated negative control PCR tube.



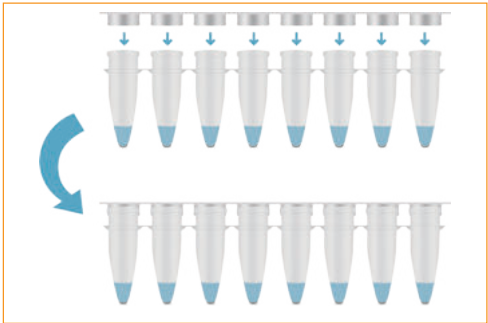
(Figure 7.7)

⑧ Add positive control: add one drop of positive control into the designated positive control PCR tube. Fasten cap of the waste tube.



(Figure 7.8)

⑨ Put on the flat cap of the 8-strip PCR tubes, tightly. Mixing by inverting the tube 3 times. Finally, swing to make sure liquid is at bottom of the tubes.



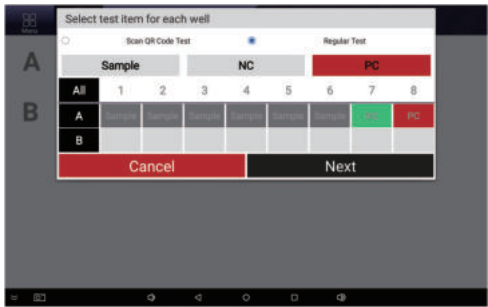
(Figure 7.9)

⑩ Loading: Open the heated lid. Load the 8-strip PCR tubes into the heating block. Press gently to make sure the tubes are in place, then close the heated lid.



(Figure 7.10)

⑪ Set sample details for each well. Refer to chapter 6.1 and 6.2 for details.



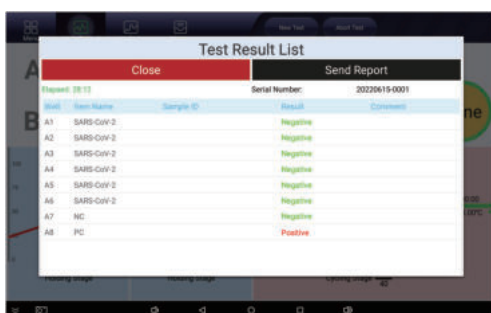
(Figure 7.11)

⑫ During the Test: Main Control view shows test timer and temperature and time of each stage. Amplification curve can be found under Analysis tab. Refer to chapter 5.3.4 for details. The heated lid status light is flashing green.



(Figure 7.12)

⑬ Test Result: when test is complete, test results and test time are shown in the Test Result List. Refer to chapter 6.4 for details. The heated lid status light is steady green.



(Figure 7.13)



1.This procedure is for demonstration on instrument operations. Please follow specific details of reagent kit use instructions when doing experiments.

2.Do not open the heated lid immediately following the test. Wait at least 5 minutes until the temperature cools down. This will help prevent potential burns and will ensure that the cap of the 8-strip PCR tubes will not pop open, avoiding any further damage to the instrument.

3.In case of power outage during experiment run. Redo the complete test when power is restored. The PCR tubes of the interrupted experiment should be disposed, because the experiment data may be inaccurate due to interruption.

Chapter 8: Troubleshooting

Observation	Possible Cause	Recommended Action
Instrument does not turn on	Power cord not plugged in properly.	Make sure both ends of the power cord are connect properly. Turn power switch to "-". If power light is on, then power supply works. If instrument still does not turn on, report issue for further assistance.
Some test wells have invalid results	There is no sample or control in that well.	Place sample into wells and setup well information.
Program aborts	Program encountered error.	Restart the program or power off and restart the instrument, then restart the program. Redo the experiment completely if necessary.
Abnormal results	Sample problems Instrument errors	Check if the sample is correct; report for repair.
Testing module self-test error on boot	AD chip damage	report for repair
Thermal control self-test error on boot	Thermal control module damage	report for repair
Temperature does not change for a long time, during heating or cooling cycle	Thermal module issues. The program should report error details.	report for repair



When the instrument malfunctions and the operator cannot find the cause, please contact sales engineer.

Chapter 9: Maintenance

9.1 Cleaning

1. Cleaning of the Surface

Clean the surface of the instrument with lint-free wipe and clear water. Wipe until the instrument is dry after cleaning. If the surface is contaminated, use 75% ethanol solution and wipe to clean.

2. Testing Wells Cleaning

Dust in the testing well could affect PCR amplification and fluorescence detection. Clean the testing wells at least once every 3 months. Use dust blowing ball to clear dust.

- Close the heated lid and put on dust cover when the instrument is not in use.
- In case the testing well is contaminated with sample, wipe clean with lint-free tissue and 75% ethanol solution.



Power off the instrument and unplug power, before cleaning.



Do not pour liquid into the testing wells or into the instrument. Do not use cleaning agents with corrosive substances or organic solvents. Inquire manufacturer or sales rep for recommended cleaning agents.

9.2 Maintenance

- Do not power on and off very frequently. After powering the instrument off, wait for at least 30 sec before turning on again
- Do not switch off immediately right after test runs. Keep power on for 10 minutes, for ventilation fan cool down the instrument, before switching off.
- Use original power cord from the manufacturer.



When the instrument has been running for over 10 hours, power off for 2 hours, before resuming experiments. Switch off power when the instrument is not in use.



Boiling bath or low temperature refrigeration (such as 4°C) in the instrument is prohibited.



Unauthorized personnel who are not from the manufacturer is not authorized to open the instrument.

9.3 Replacing the Fuse

There are two 10A fuses on the instrument for protection. When the fuse is failed, operator can follow steps below to replace fuse:

1. Switch off and disconnect power cord.
2. Use a flathead screwdriver to remove the fuse holder.
3. Replace the fuse ($\Phi 5 \times 20\text{mm}$ - F10AL250V).
4. Install the fuse holder back to the instrument and reconnect the power cord.



Make sure power is switched off and power cord is disconnected before replacing fuse.

9.4 Waste Disposal

After a test run, the PCR tubes contain amplified sample. Follow local lab regulations to dispose the waste, to avoid contamination of the laboratory and instruments.



Do not open the PCR tube after the test, to prevent the high concentration nucleic acid solution from contaminating the laboratory.

9.5 Overheat Protection

The heating module on the instrument has not overheat protection. In case temperature raises over threshold, the thermal protection disconnects and cannot be restored. Heating module would not heat properly.



In case overheat incident happens to the heating module. Stop using the instrument and contact manufacturer for repair.

Chapter 10: Testing Control

Please follow the instructions below to perform proper maintenance and ensure accurate detection of the instrument:

- ① Regularly use the negative and positive controls come with the reagent kit to validate detection effectiveness.
- ② Each quantitative test must include reference standards, as well as negative and positive controls to assure test validity and benchmark detection results.

















Chapter 11: Manufacturer and After-Sales Contact

Company Name: Wuxi Opulen Technology Co., Ltd.

Address: 100 Dicui Rd.,
Block 6, 3rd Floor,
Wuxi, Jiangsu Province, 214072, People's Republic of China

Contact Number: +86-510-8516 7117

12.3 Symbols

	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™