深圳市尚维高科有限公司
Shenzhen Shineway Technology Corporation

PCR Nucleic Acid Analyzer
（SWM-01）

Instruction Manual

Technical requirement No: Q/SWM01201801

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Product life: 5 years

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EC REP N/A

CE IVD

Preface

Thanks for choosing PCR Nucleic Acid Analyzer SWM-01. The manual instruction mainly illustrates the function and operation procedures of the devices. Please read this instruction manual carefully to ensure the proper use. Please keep this instruction manual. If encountering any problem while using, please refer to the manual instruction.

Open-package Inspection

Please check the device and the accessories in accordance with the packing list after opening the package carton. If any problem is found, such as wrong device or accessories, missing accessories or defective accessories, please contact the distributor or the manufacturer.

Contents

Symbol Interpretation

The symbols listed below are applicable to this instruction manual only.

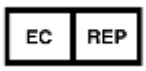
Table A

Symbol	Meaning
	Notice! This might cause damages on the device or affect the test result.
	This might cause the biological contamination.
	This might cause electric shock
	High Temperature. This might result in bodily injuries.
	Hard Light. This might result in eye injuries.
	This might result in bodily injuries.
	Flammable Material. This might cause a fire.

Silk Printing and Label

The silk printing and labels listed below are applicable to this instruction manual only.

Table B

Symbol	Description of symbol
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Indicates the medical device manufacturer.
	Indicates the date when the medical device was manufactured.
	Indicates the authorized representative in the European Community.
	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
	Power switch / Power on state
	Operating status
	Stop running status
USB	Data Transfer Interface
Fuse	Fuse

Figure

All the figures listed in this instruction manual are only for illustration or example purposes.

1 Summary

1.1 Introduction of the Device

PCR Nucleic Acid Analyzer SWM-01 performs qualitative detection of nucleic acid samples (DNA/RNA) derived from human body by single fluorescence PCR, including nucleic acid detection and gene analysis of pathogens. The product can be used under various scenarios including CDC, emergency medical treatment, specialist examination, primary care and blood screening. The instrument consists of the control system, power system, photoelectric system, temperature control system, case component, reaction chips, software modules (including control software, version 1.0).

Features:

- 7.5inch colorful touch screen with a user-friendly control surface;
- Streamlined shell design with stylish appearance;
- Low reagent consumption, saving detection cost, and improve the efficiency of PCR reaction;
- High detection sensitivity;
- Advanced design of optical path to eliminate interference of the external light and further increase detection reliability;
- Employ accurate and efficient data processing system with artificial intelligence image segmentation algorithm;
- Equipped with a large-capacity USB flash drive for data storage.

1.2 How to Use the Instruction Manual

The instruction manual gives an introduction of how to operate this PCR Nucleic Acid Analyzer SWM-01 safely and effectively.

- Chapter 1 illustrates the information of instruction manual;
- Chapter 2 illustrates the basic information of PCR Nucleic Acid Analyzer SWM-01;
- Chapter 3 illustrates how to assemble the device and the software operation;
- Chapter 4 illustrates the date analysis function of PCR Nucleic Acid Analyzer SWM-01;
- Chapter 5 illustrated how to properly maintain PCR Nucleic Acid Analyzer SWM-01;
- Chapter 6 illustrates how to deal with machine faults and maintenance information.

1.3 Important Safety Operation Information

Before safely operating PCR Nucleic Acid Analyzer SWM-01, the user must have a complete understanding on how the device operates, and please read this instruction manual carefully before using PCR Nucleic Acid Analyzer SWM-01.

Below are the warning signs of PCR Nucleic Acid Analyzer SWM-01. If ignoring, it might pose a threat to the personal safety. This list is in no particular order of importance. Please read it carefully and take preventive measures.

1.3.1 Safety

Table 1-1

	**Electric Shock** （1） When the power is on, please do not open the panel and the anti-collision box except for those authoritative operators. （2） Please avoid any liquid splashing on the table. If any liquid flows into the device, please shut down the power immediately and do not hesitate to contact the after-sales staff from Shenzhen Shineway Technology Corporation.
	**High Temperature** （1） When the product is performing PCR amplification reaction, don't open the cover and don't touch high temperature objects such as chip and heater.
	**Biological Contamination** （1） The operator should take protective measures and prohibit direct contact with biochemical reagents and reactants，because there is operation of biochemical reagents during the product use. （2） All the tips, sample test tubes, and disposable microfluidic chips should be considered contagious. Gloves should be worn when in contact. Discharge and treatment of biological waste should be in accordance with the regulations and laws of local Health and Environmental Department.
	**Flammable** （1） Don't use flammable hazardous such as alcohol or ether near the PCR device.

Hard Light

（1） Don't gaze the light on the PCR device with the naked eyes to avoid threats to the eyes.

1.3.2 Notice

Table 1-2

Application Scope

（1） The product adopts a rapid fluorescence qualitative and quantitative PCR system for detection of nucleic acid samples (DNA/RNA) derived from human body, including nucleic acid detection and gene analysis of pathogens.

（2） Product can also be used together with the matched detection reagents to detect food-borne pathogens, food origin, GMF identification, plant bacteria and viruses, animal diseases, etc.

Operator

The operator must be an inspector with biological knowledge and needs to own the following capabilities:

（1） Practised basic skills in molecular biology experiments;

（2） Master the basic knowledge of molecular biology;

（3） Correct operation of the PCR device;

（4） Correctly analyze the sample fluorescence quantitative test results.

Application Environment

（1） Install PCR device properly in accordance with the installation environment specified in this instruction manual. Installation and use out of accordance with the specified conditions may result in unreliable results and damage to the PCR instrument.

（2） Not to position the equipment so that it is difficult to operate the disconnecting

	device. （3） If you need to change the working environment of the PCR machine, please contact the Shenzhen Shineway Technology Corporation or the agent in your area.

Electromagnet Interference

（1） The PCR device is susceptible to electromagnetic interference during operation, which may affect the measurement results and cause malfunctions. Please do not use equipment such as electric drills, mobile phones, walkie-talkies, etc. that generate electromagnetic waves during operation.

（2） The electromagnetic wave will be radiated outside during the operation of the PCR instrument. Don't install or use electromagnetic sensitive equipment near the PCR instrument.

Ground Fault

（1） The power supply must be properly grounded, otherwise there may be a risk of electric shock;

（2） The grounding impedance must be less than 10 Ω. Poor grounding may result in unstable results and leakage of the casing, causing a risk of electric shock.

Water Quality

（1） According to the provisions of GB/T 6682-2008 "Analysis Laboratory Water Specifications and Test Methods", the water quality used in the experiment is Grade 1 water, and the water quality must meet the following requirements. Otherwise, the experiment may fail, and make the error testing results.

- Particles less than 1 units/ml;
- The resistivity is greater than 18 MΩcm;
- The number of colonies is less than 1 cfu/ml;
- The dissolved silicon is less than 0.01 mg/L.

Analytical Parameters

（1） Incorrect experimental parameters may lead to erroneous measurement results, please contact Shenzhen Shineway Technology Corporation for more details.

1.4 After-sales Service Warranty

Our company is responsible for returning the instrument due to defects in materials and manufacturing within one month from the date of delivery.

Our company provides the instrument with a free warranty due to the faults caused by defects in materials and manufacturing within 12 months from the date of delivery. During the warranty period, the company will selectively repair or replace the instruments that prove to be defective.

Warranty Scope

Damage caused by improper operation of the user, use under unsatisfactory conditions, unauthorized repair or modification, etc., is not covered by the warranty.

After the warranty period, the maintenance cost is appropriately charged according to the repair items.

2 Design and Illustration

2.1 Parameters

2.1.1 Basic parameters

Table 2-1

Technical Index	Parameters
Temperature Control Range	40-105℃
Heating Rate	≥1.5℃/s
Cooling Rate	≥1.5℃/s
Temperature Accuracy	±0.5℃
Temperature Uniformity	±1℃
Chip Reaction Volume Range	2 μL
Fluorescence Channel	FAM
Input Voltage	AC100~240V（50/60Hz）
Net Weight	2.5kg
Dimension	330mm×250mm×180mm（exclude packaging）
Operating Software	PCR Nucleic Acid Analyzer control system 1.0
Hardware version	PCR Nucleic Acid Analyzer hardware system V1.0
Operating System	Linux system
Signal Interface	USB, Ethernet

2.1.2 Functionality index

2.1.2.1 Module operating temperature range

a) Module minimum operating temperature: 40°C, error: ±1°C;

b) Module maximum operating temperature: 105°C, error: ±1°C.

2.1.2.2 Average heating rate of the module: from 50°C~90°C，≥ 1.5°C/s.

2.1.2.3 Average cooling rate of the module: from 50°C~90°C，≥ 1.5°C/s.

2.1.2.4 Module temperature control accuracy (temperature control fluctuation): ≤±0.5°C.

2.1.2.5 Module Temperature Accuracy:

Difference between measured temperature and the set temperature ≤ ±0.5°C.

2.1.2.6 Module temperature uniformity:

Temperature difference ≤ ±1.0°C.

2.1.2.7 Temperature Duration Accuracy:

The relative deviation of the actual temperature duration from the set temperature duration is ≤ ±5.0%.

2.1.2.8 Fluorescence intensity detection

a) Repeatability of fluorescence intensity detection (intra-assay measurement repeatability):

Repeatedly detect the high-, medium-, and low-concentrated calibration dye, and the coefficient of variation (CV) shall be ≤ 3.0%.

b) Repeatability of sample detection (intra-assay measurement repeatability):

Repeatedly detect the high-, medium-, and low-concentrated nucleic acid samples, and the coefficient of variation (CV) of the Ct value (or the logarithm of the concentration) shall be ≤ 3.0%.

2.1.2.9 Linearity

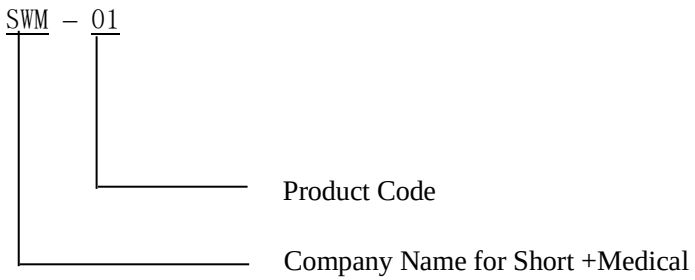
a) Sample linearity

A serial dilution of samples (at least 5 concentrations) shall be detected, and the Ct value of each concentration and the logarithm of each concentration shall has a linear regression coefficient of r ≥ 0.990;

b) Fluorescence linearity

A serial dilution of fluorescent dye (at least 5 concentrations) shall be detected, and the fluorescence intensity and the dilution ratio of each concentration shall has a linear regression coefficient of r ≥ 0.990.

2.2 Model



2.3 Product Usage

Based on the principle of fluorescent polymerase chain reaction, the product is clinically only used with specified IVD reagents (approved by local medical device management department) for qualitative detection of nucleic acid samples (DNA/RNA) derived from humans, including nucleic acid detection and gene analysis of pathogens. The clinical sample includes serum or plasma sample, throat swabs, eye or tooth secretions, tissue slice and etc. from human. The operator should be an inspector of a professional medical facility and must have the following capabilities:

1. Practiced basic skills in molecular biology experiments;
2. Master the basic knowledge of molecular biology;
3. Correctly regulate and operate PCR Nucleic Acid Analyzer;
4. Analyze the test results of fluorescence quantitative properly.

2.4 Mechanism

A silicon-based thin film microheater is used as a rapid heating component, and a microfluidic chip is used as a carrier for the PCR reaction. The PCR reaction system uses a fluorescent probe as an indication of the reaction signal. As the PCR reaction progressed, the fluorescence of the positive reaction will accumulate, and the signal is collected as images by a CMOS camera. Finally, the control system completes data collection and makes digital image processing.

2.4.1 Control Systems：Embedded Control Systems

2.4.2 Temperature Control：Based on Joule heating principle, a silicon thin film micro-heater with metal coating is used as a heating element, which has high thermal conductivity and good temperature-resistance linear curve, thereby achieving rapid and accurate temperature rise. In addition, the cooling system is equipped with a high-speed and small fan and an optimized duct was designed to effectively increase the cooling rate.

2.4.3 Reaction Carrier：The silicon-based microfluidic chip can be used as a disposable carrier for the PCR reaction. The internal reaction chamber has a volume of 2 μL. The silicon substrate is tightly contacted with the thin film micro-heater, which is beneficial to improve heat transfer efficiency and temperature uniformity. Covering the silicon substrate with a glass wafer to form a PCR reaction chamber can effectively avoid sample contamination.

2.4.4 Fluorescence signal detection: The reaction system of PCR utilize a fluorescent probe or a general dye as an indication of the signal. As the PCR reaction proceeds, the fluorescence of the positive reaction will accumulate and the signal is collected as images by the CMOS camera. At last, the control system completes data collection and processing.

2.5 Product Composition

Table 2-2

No.	Item	Model	Unit	Qty	Note
1	PCR Nucleic Acid Analyzer	SWM-01	Set	1	
2	Power Cord	0.75mm2*3，1.5m	Pcs	1	Accessory
3	USB Flash Drive	16GB	Pcs	1	Accessory
4	Instruction Manual		Set	1	Attaching File
5	Warranty Card		Set	1	Attaching File
6	Certificate of Quality		Set	1	Attaching File

2.6 Structure

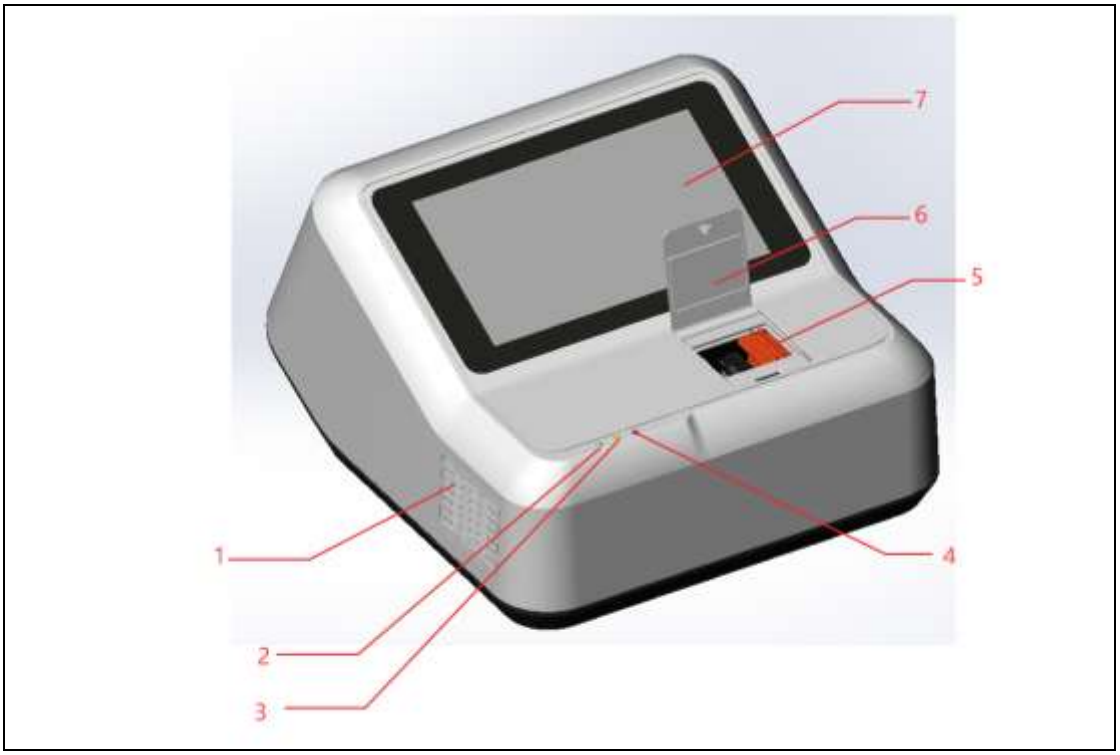


Figure2-1

1 Air Inlet 2 Power Indicator 3 Running Indicator 4 Fault Indicator 5 Reaction Chip Holder 6 Cover of the Reaction Room 7 Touch Screen

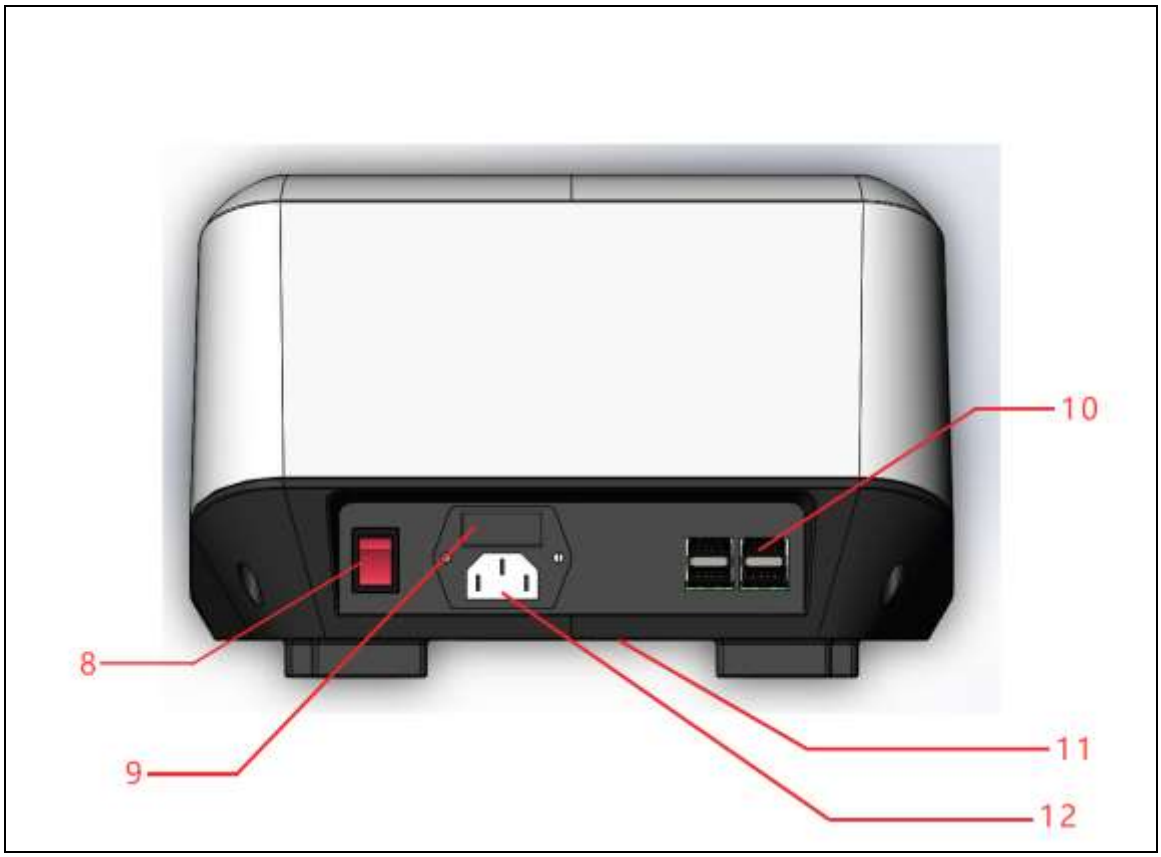


Figure2-2

8 Power Button 9 Fuse Holder 10 USB Interface 11 Air Outlet 12 Supply Hub

2.7 Indicator State Description

Table 2-3

Indicator State	Instrument State
○○○	Power off
●○○	Power on
●●○	Running
●○●	Fault

3 Assembly and Operation

3.1 Instrument assembling

After unpacking, there is no additional installation for PCR Nucleic Acid Analyzer SWM-01. The user must use the supporting microfluidic chip as reaction carrier for experiment. In addition, the user also needs to prepare the pipette, EP tube and other basic experimental accessories for molecular biology experiment.

One end of the matching power cord is connected to the Supply Hub 12 of the instrument, and the other end is connected to the earthed socket. Always use the matching power cord to connect the instrument to a suitable power source. The voltage of the power supply should meet the requirements of the instrument.

3.2 Sample preparation and introduction

3.2.1 Sample preparation

The clinical sample(serum or plasma sample, throat swabs, eye or tooth secretions, tissue slice）should be processed for nucleic acid extraction by using a related kit and then stored at -20 ℃ or -70 ℃ for no more than 3 months, and the samples cannot be frozen and thawed more than 4 times.

After thawing the sample, add the PCR kit according to the relevant instructions, and then proceed to 3.2.2.

3.2.2 Sample introduction

After sample preparation, aspirate the reaction solution in the EP tube by pipette, and then the pipette tip was pressed against the chip inlet, and the reaction solution entered the chip under the action of capillary force. Finally, the chip sealing cap was stoppered above the chip roof. (As shown in the figure below)

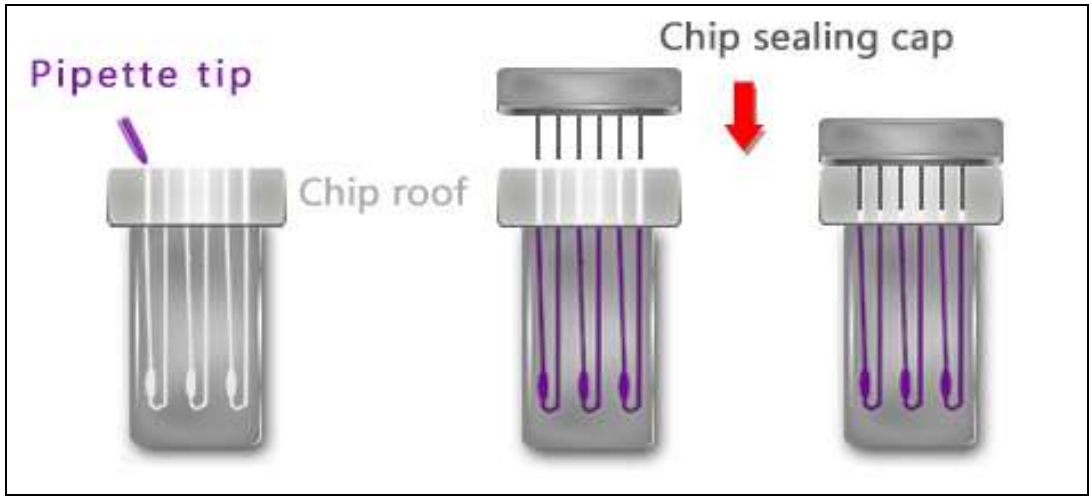


Figure3-1

Open the Cover of the Reaction Room 6 of the instrument and insert the chip into the reaction chamber, and then press the Reaction Chip Holder 5 to clamp the chip. Finally close the cover and set the experimental parameters.

3.3 Startup of software

The software version currently used by the instrument is "PCR Nucleic Acid Analyzer control system V1.0".

3.3.1 Turn on the Power Button 8, the instrument automatically starts the PCR Nucleic Acid Analyzer control system V1.0, and the following interface appears：

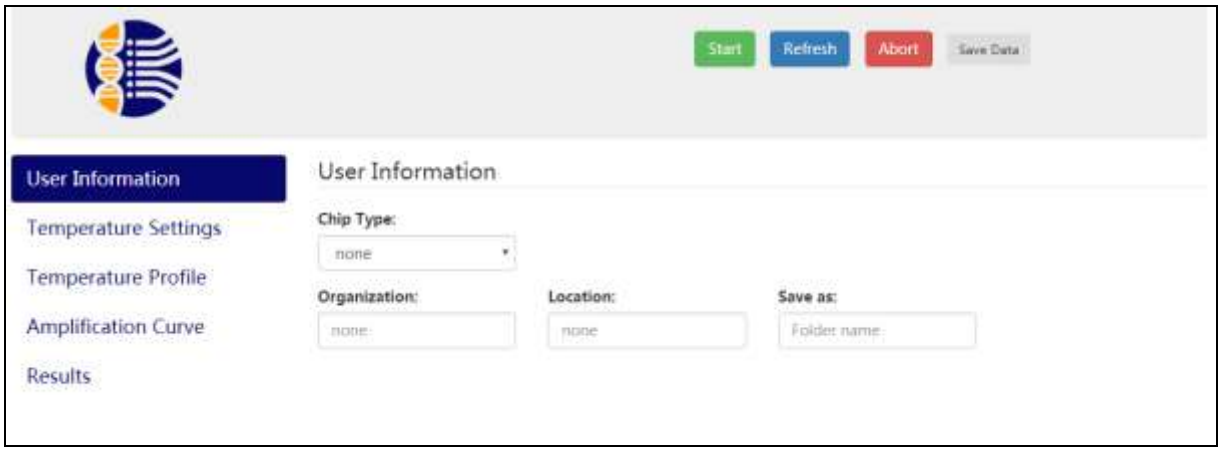
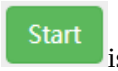
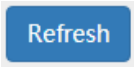
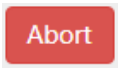


Figure3-2

3.3.2Enter the operating interface，the function of the buttons are listed as follow: 

is a data saving button， 

is a start button of reaction， 

is a refreshing button for resetting input information and restarting reaction， 

is a abort button for stopping reaction.

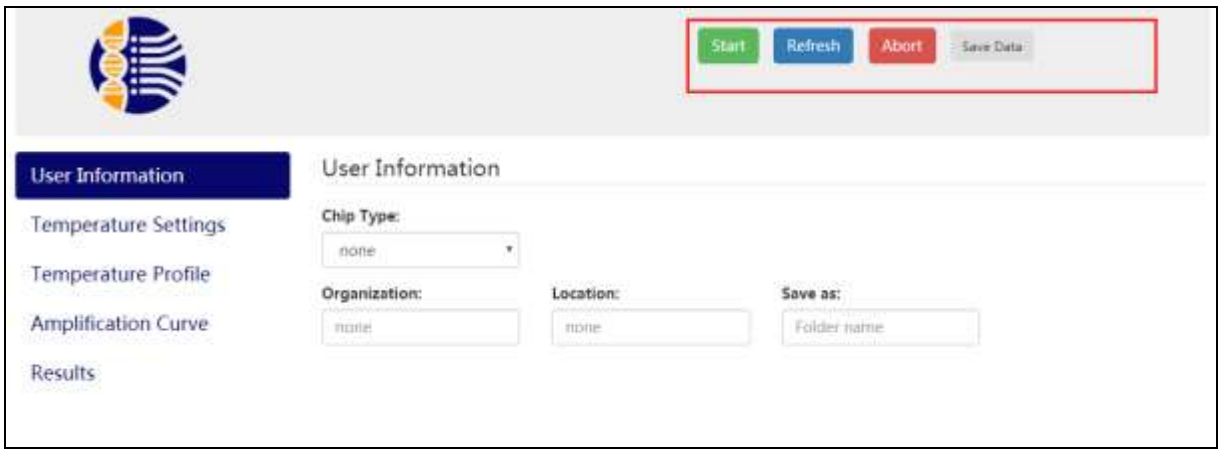


Figure3-3

3.3.3 Choose "Chip Type" and enter the user information, the sample name of each well and the folder name in turn.

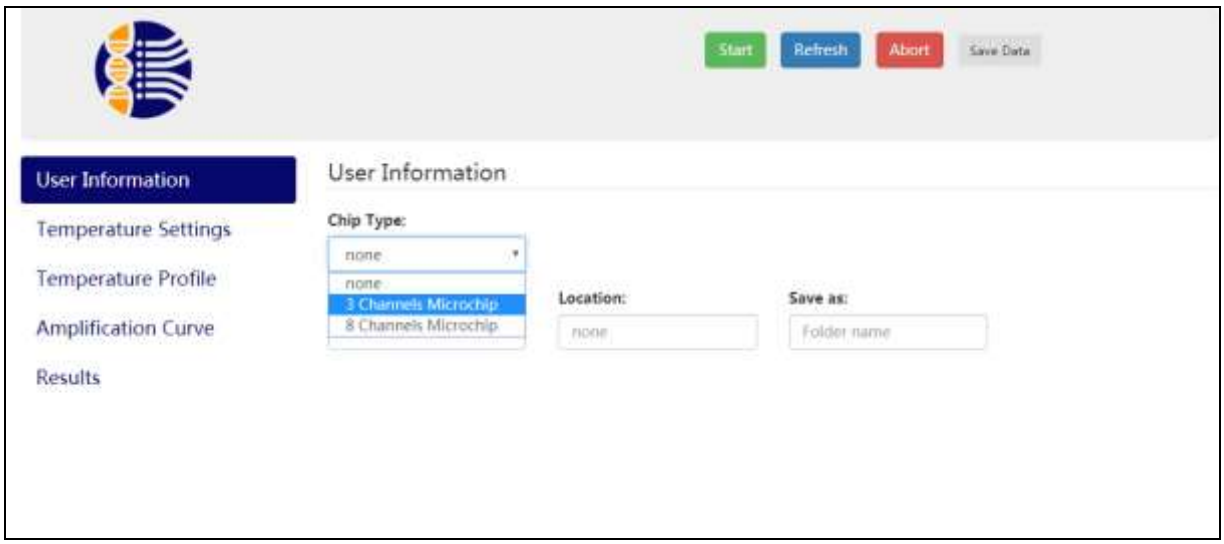


Figure3-4

3.3.4 Fill in the user information as follows：

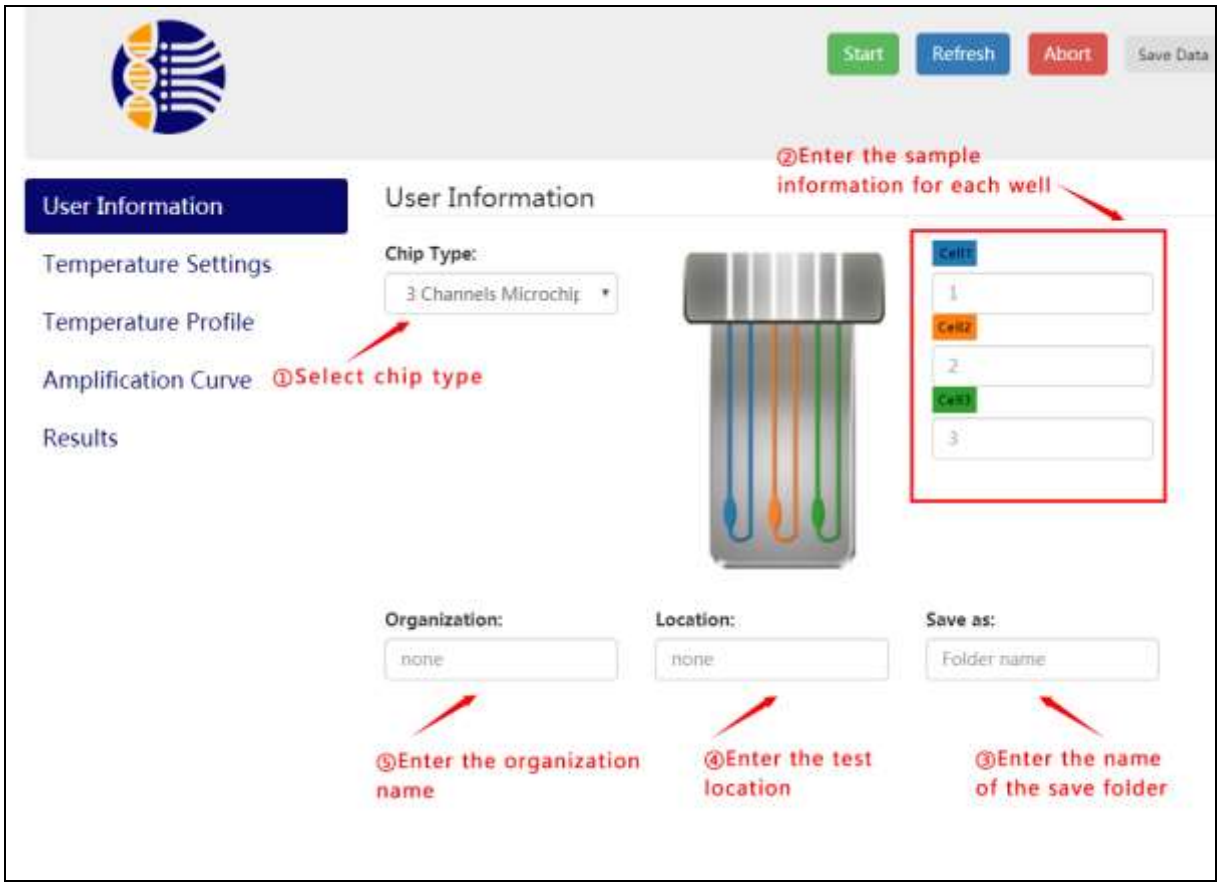


Figure3-5

3.3.5 Click "Temperature Settings" and select "Detection Item".

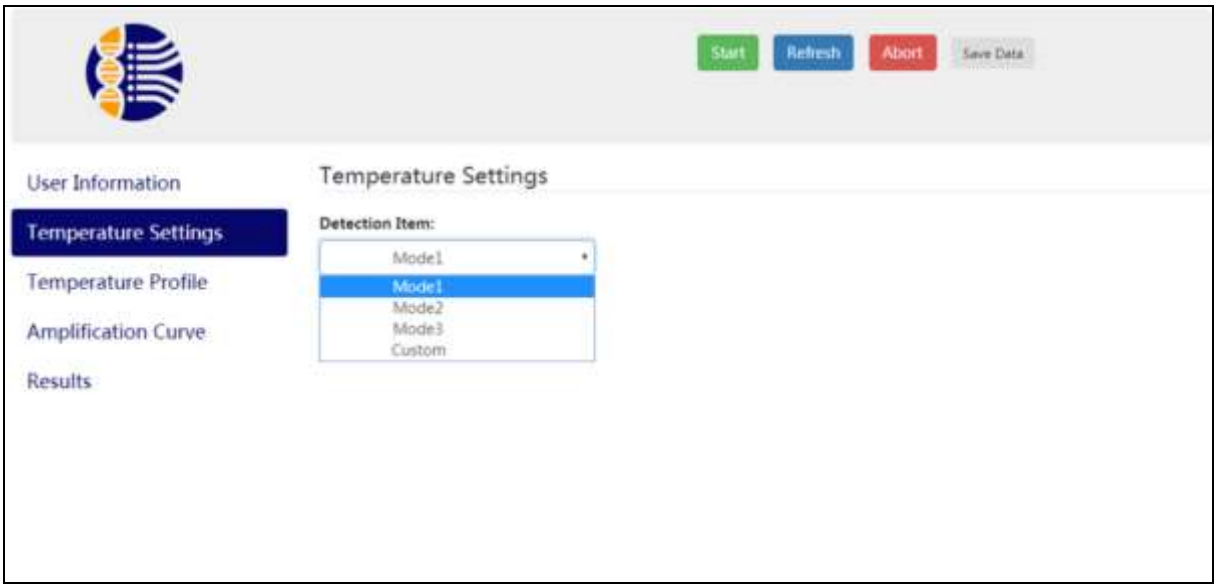


Figure3-6

3.3.6 If you select the "custom" mode, set the parameters in turn according to the experimental requirements. (Note: The temperature setting cannot be higher than 105 °C; the cycle time of collecting the fluorescence stage is not less than 20s.) “Add New” is a button for adding a new temperature setting, and “Remove” is a button for removing a temperature setting.

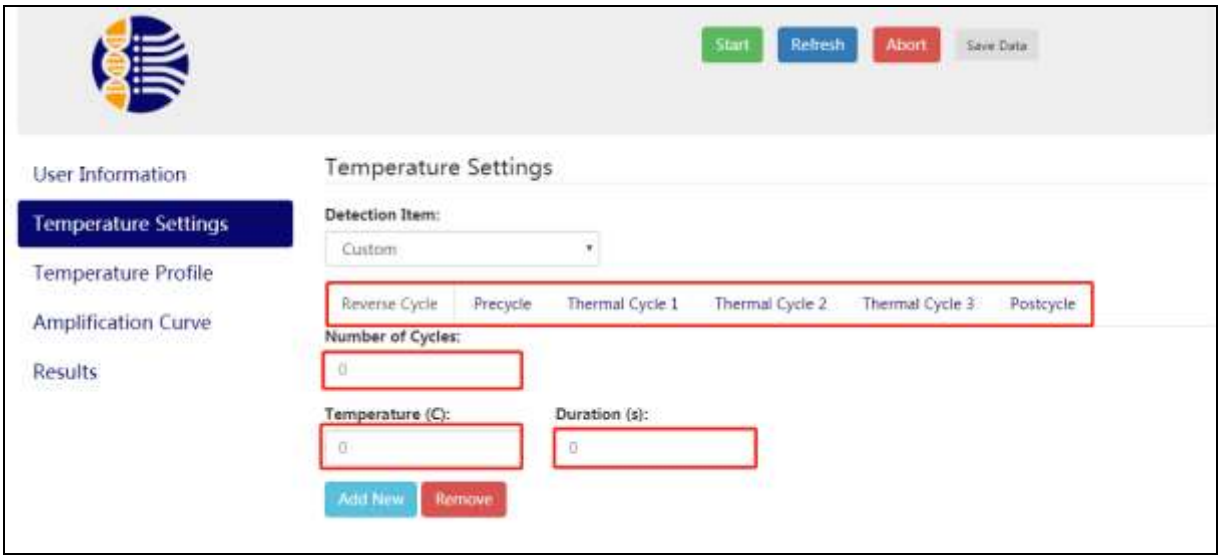


Figure3-7

3.3.7 After completing the test parameter settings, click the “Start” button, then the reaction starts. The interface automatically jumps to the “Temperature Profile” page.

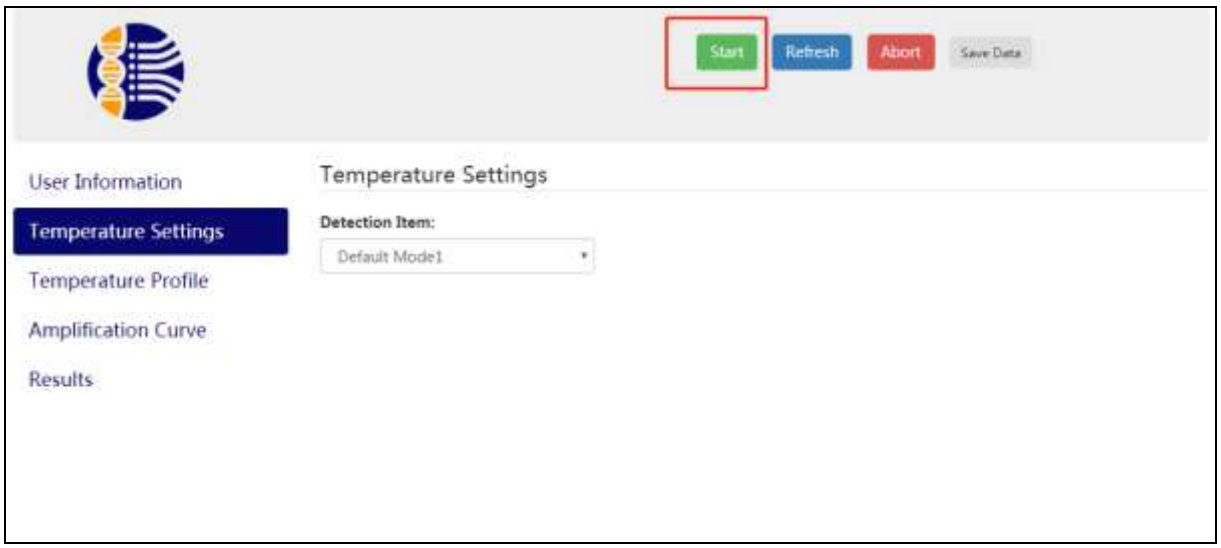


Figure3-8

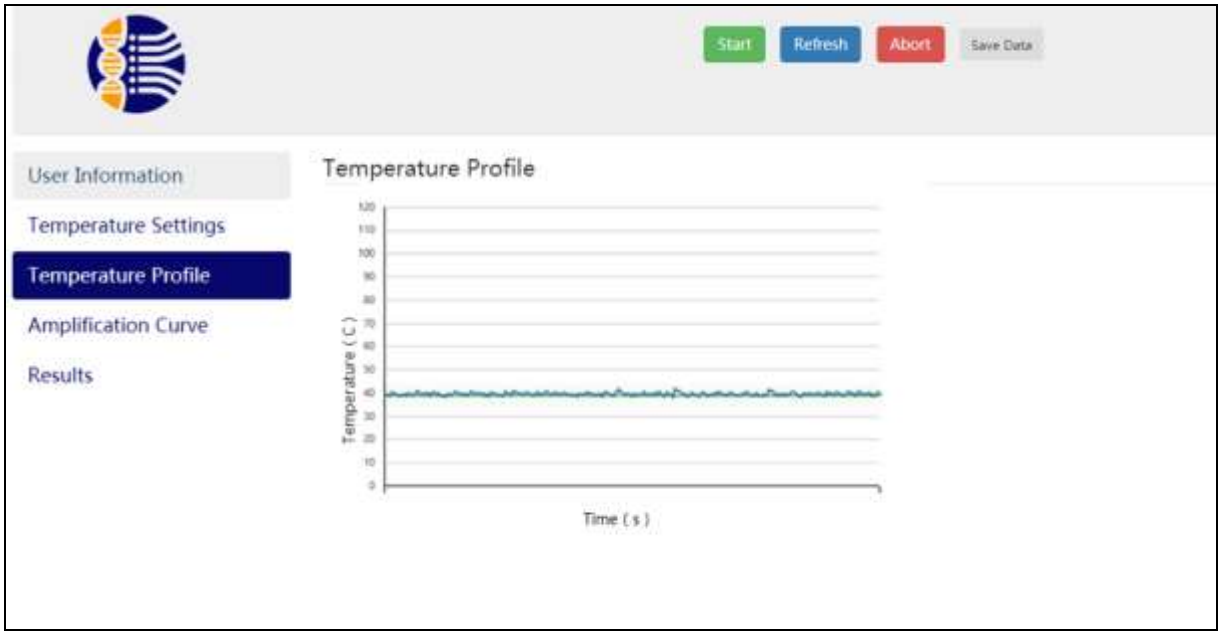


Figure3-9

3.3.8 During the reaction, the user can click on the "Amplification Curve" to observe the reaction results for each cycle in real time.

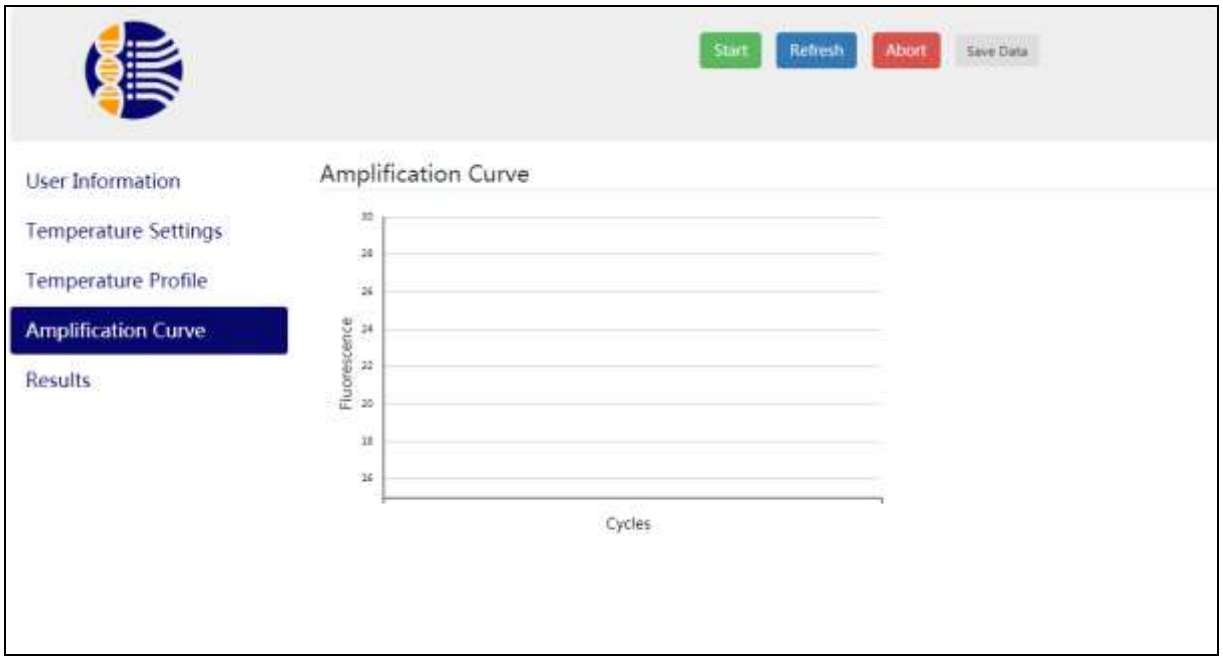


Figure3-10

3.3.9 After the reaction is finished, the instrument automatically pops up the result window. (Here is a positive sample as an example)

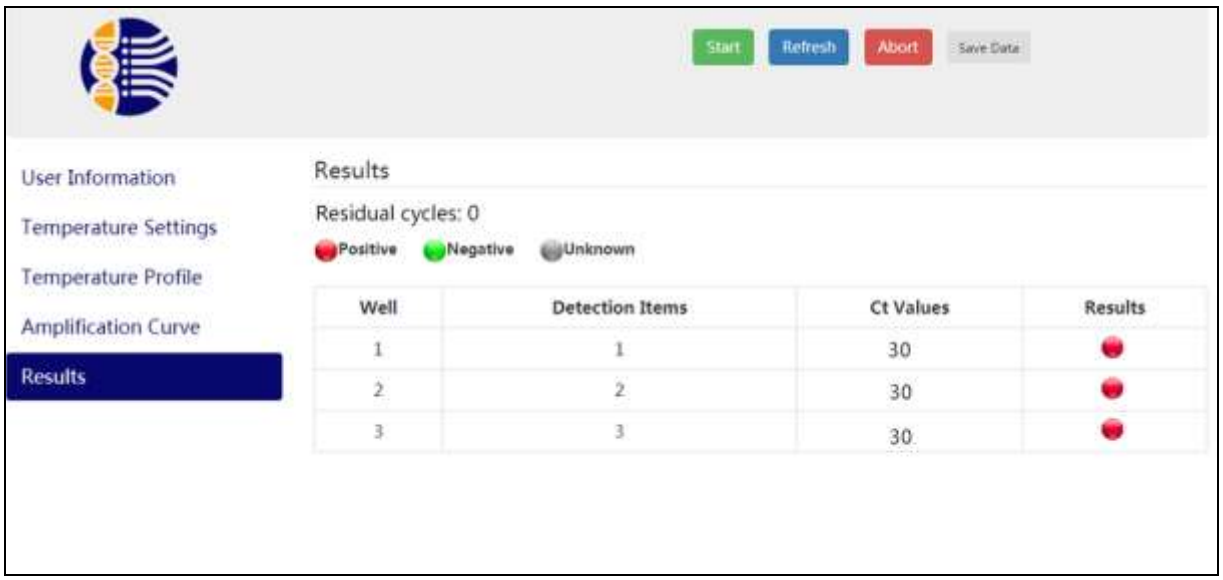


Figure3-11

3.3.10 After clicking "Abort", you can insert a USB flash drive on the USB interface 2 and click the “Save Data” button to complete the data transfer. Then the interface will Pop-up prompt box "Save Succeed".

Figure3-12

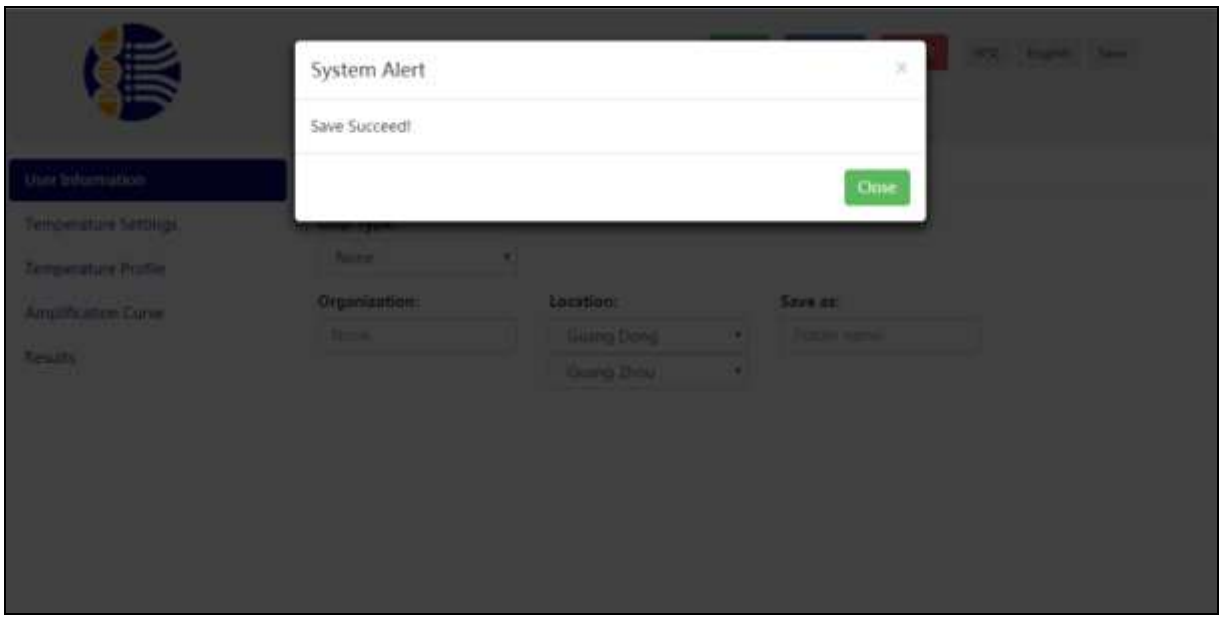


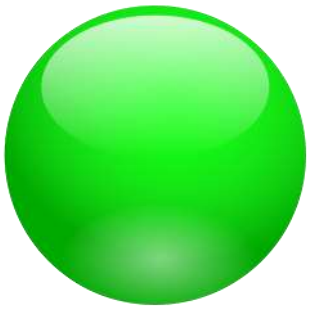
Figure3-13

3.3.11 To start the next experiment, click the “Refresh” button and repeat steps 3.3.3 to 3.3.10.

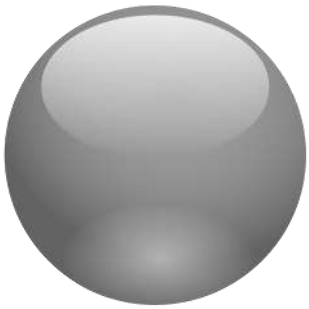
4 Data Analysis

These following symbols represent the reaction result and their meaning are listed as below.

It means the reaction result is positive.



It means the reaction result is negative.



It means the reaction result is unknown.

Figure4-1

5 Maintenance and Cleaning

5.1 Operating Conditions

In order to achieve the safety and performance reliability requirements of the PCR Nucleic Acid Analyzer, the environment in which the instrument is installed should meet the following conditions:

- Non-explosive environment
- Normal atmospheric pressure (altitude below 3000m)
- Pollution degree 2 or higher
- Ambient temperature is 10℃～30℃
- Relative humidity is 10%～70%
- Input power is AC100~240V（50/60Hz）
- Avoid exposing the instrument to excessive heat
- Avoid accidental liquid splashing into the instrument
- Ensure that the air temperature at the air inlet of the instrument is lower than 30℃

5.2 Transportation and Storage Conditions

- Ambient temperature is 0℃～55℃
- Ambient pressure is 86.0kPa~106.0kPa
- Relative humidity is lower than 80%
- Transportation method：Put the instrument into a carton with anti-collision cotton, and move it normally to avoid severe vibration.
- Placement Location：Put the instrument in a horizontal position.

5.3 Cleaning

Table5-1

	When the instrument stop working, the power should be turned off. Every one year, a known test sample is used to verify that whether the instrument requires calibration.
	Regularly clean the reaction chamber, micro-heater and top cover with a clean soft cloth dampened with absolute alcohol (recommended once a month). It is good for sufficient contact between the chip and the heater, good thermal conductivity, and avoiding contamination. The power must be turned off when cleaning the instrument. It is strictly forbidden to drip the cleaning agent into the reaction chamber. Do not wipe micro-heater with excessive force in case of crushing .The surface of the instrument can be cleaned with a soft cloth

	dampened with a mild detergent.
	Check the power cord regularly. When the power cord is aging and damaged, please replace a new one of the same specification in time.

5.4 Instrument validation

The instrument is calibrated at the manufacturer. No additional calibration required for customer.

5.5 Waste disposal

After experiment, there are a large number of amplification products in the chip. According to the local regulations, the waste should be treated as soon as possible to avoid contamination of the environment and instruments.

Do not open the chip cap after reaction, otherwise the high concentration of nucleic acid aerosol will contaminate the environment.

5.6 Waste instrument disposal

When the instrument reaches its expiry date, the user should contact the supplier or manufacturer to recycle the waste products. In addition, the user also can dispose of waste equipment in accordance with local regulations. Do not discard the instrument with other household waste to avoid environmental pollution.

6 Fault Diagnosis and treatment

This chapter mainly introduces the possible fault, causes and treatment methods of the instrument. When the fault is not in the table below, you should contact the supplier or manufacturer to inquire solution.

Table6-1

No.	Phenomenon	Reason	Solution
1	Power status indicator does not light after turning on the power switch	The power cord is not connected properly	Check if the power cord is connected properly or replace the power cord.
		Fuse burned	Open the fuse holder and replace the fuse of the same specifications
		Switch damage	Contact the supplier or manufacturer
		Others	Contact the supplier or manufacturer
2	No display on the screen	There is a poor contact between the plug and the power supply system.	Make sure that the plug and the power supply system are fastened.
		Fuse is overloaded	Check if the fuse is overloaded.
3	Fault indicator is on	The instrument stops running due to a fault.	Restart the instrument. Contact the supplier or manufacturer if the fault indicator is still on.
4	Temperature error	Temperature sensor is damaged	Contact the supplier or manufacturer
		Program failure	
		The ambient temperature is not maintained between 15-35 ℃.	Make sure that the ambient temperature is maintained between 15-35 ℃
5	The instrument heating module is overheated, and the screen pops up the dialog box “Temperature is too high, the program is automatically terminated”. In the meanwhile the buzzer sounds for 5 seconds, and the reaction is terminated.	If the heating system fails and the temperature exceeds the limitation of the allowable range, the protection device will automatically disconnect and cannot be recovered.	Stop using the instrument and contact the supplier or manufacturer.
6	Rising and falling of temperature are obviously	Ventilation holes are blocked	Clear obstructions at the vents

	slow or temperature control is not accurate	Micro heater or fan is damaged	Contact the supplier or manufacturer
		Temperature sensor is damaged	
7	Unable to capture photos	Camera lens is damaged	Contact the supplier or manufacturer
		Cable disconnection	
		The system pops up a dialog box prompting "Cycle duration with detect fluorescence selected YES should be over 20 seconds"	The cycle time of collecting the fluorescence stages should set up more than 20s
8	Location of image acquisition is different	Camera lens shift	Contact the supplier or manufacturer
		Chip card slot damage	
9	Fluorescence detection value is abnormal	Strong external light source	Turn off the external light source
		Photoelectric system damage	Contact the supplier or manufacturer
10	Timing error	Program error or clock battery is exhausted	Contact the supplier or manufacturer
11	A pop-up dialog box prompts "Please insert a USB flash drive"	No USB flash drive is inserted.	Insert the USB flash drive at the USB interface 10 according to the instructions manual.
12	A pop-up dialog box prompts "Save failed"	U disk doesn’t have enough storage space.	Clean up the historical data of the U disk.
		U disk is not compatible with the instrument.	It is recommended to use the matching USB flash drive or reformat the USB flash drive before using.

7 Appendix

Appendix I Electromagnetic compatibility warning

The PCR Nucleic Acid Analyzer SWM-01 is in line with the emission and immunity requirements specified in IEC 61326-1:2012 and IEC 61326-2-6:2012. The user has the responsibility to ensure the electromagnetic compatibility environment to make the device work normally. Therefore, you can evaluate the electromagnetic environment before the use of the device.

Table7-1 Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment - guidance
Radiated emissions CISPR11	Group 1	The PCR Nucleic Acid Analyzer SWM-01 RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emissions CISPR11	Class B	The PCR Nucleic Acid Analyzer SWM-01 is suitable for use in professional healthcare environments, but if used directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, whatever additional measures are necessary.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC61000-3-3	Not applicable	

Table7-2 Electromagnetic Immunity

Test item	EMC basic standards	Test value	Compliance
Electrostatic discharge (ESD)	IEC 61000-4-2	Air discharge: 2kV, 4kV, 8kV, Contact discharge: 2kV, 4kV	A
Radiated RF electromagnetic Fields	IEC 61000-4-3	3V/m, 80MHz-2.0GHz, 80%AM	A
Power-frequency Magnetic Fields	IEC 61000-4-8	3V/m, 50Hz	A
Voltage Dips, Interruptions, and variations	IEC 61000-4-11	1 cycle 0%; 5 cycles 40%; 25 cycles 70% 5%, duration: 250 cycles	A
Electrical Fast Transients and bursts	IEC 61000-4-4	1kV (5/50ns, 5KHz)	A

Surges	IEC 61000-4-5	Line to ground: 2kV line to line: 1kV	A
Conducted Disturbances, induced by RF fields	IEC 61000-4-6	3V/m, 150KHz-80MHz, 80%AM	A

Warning: This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

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