FQ-8A
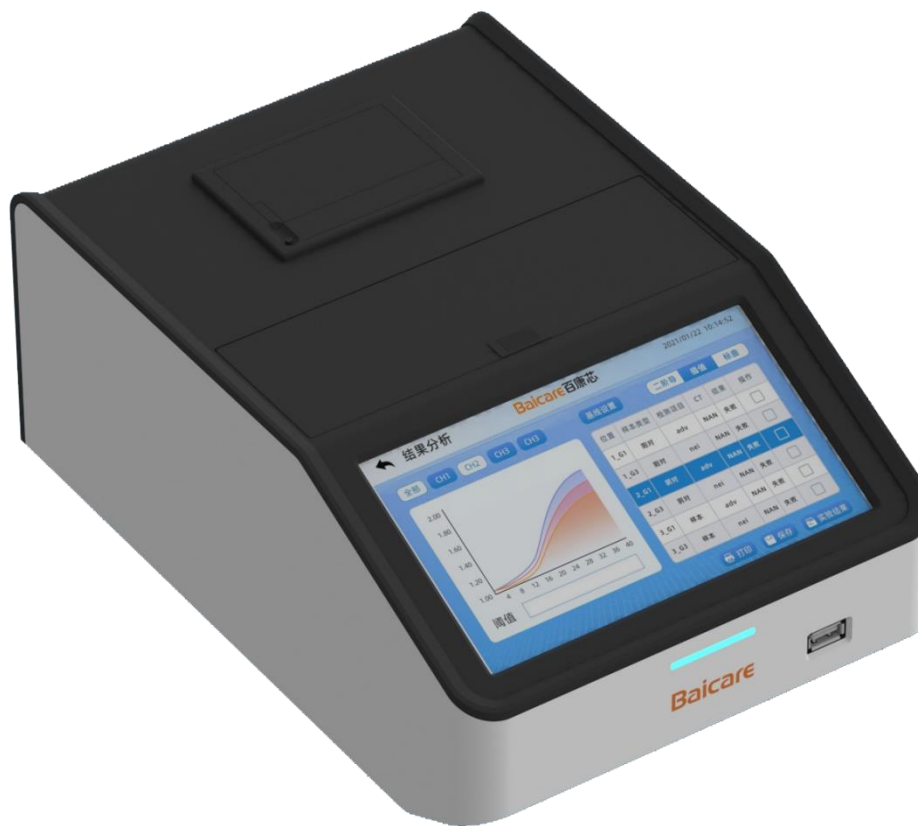# Ultrafast QPCR Device
User manual
Version 1.0

End User License Agreement

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This Agreement is governed by the laws of the People's Republic of China.

For any disputes arising from this Agreement, both parties shall negotiate in accordance with the principles of friendship and honesty. If negotiation fails, Beijing Arbitration Commission shall be selected for arbitration.

Baicare reserves the final right to interpret this Agreement.

If you have any questions about this Agreement, please contact Baicare (Tianjin) Biotechnology Co., Ltd. The contact information is:

Address: 1st-5th Floor, Building C4, International Enterprise Community, Changyuan Street, Wuqing Development Zone, Tianjin

Zip code: 301700

Tel: 400-898-0905

Email: support@bai-care.com

sales@ bai-care.com

Website: http://www.bai-care.com

Life time:

5 years.

Registration address: 1st-5th Floor, Building C4, International Enterprise Community, Changyuan Street, Wuqing Development Zone, Tianjin

Production address: 1st-5th Floor, Building C4, International Enterprise Community, Changyuan Street, Wuqing Development Zone, Tianjin

Medical device production license number:

Medical device registration certificate number:

Technical requirement number of products:

Date of preparation or revision of the specification:

Table of contents

Preface

Welcome to use the *Ultrafast QPCR Device User Manual*. This manual is suitable for guiding the installation, operation and maintenance of the Ultrafast QPCR Device produced by Baicare (Tianjin) Biotechnology Co., Ltd. Before installation and operation, users should read this manual carefully, operate according to the manual, and understand various precautions.

Content of the Manual

Table 0-1 Introduction to Content of the Manual

Chapters	Overview
Important safety information	In order to use this system safely, users should read this chapter carefully before installing or using it.
Hardware installation	Instructions to Ultrafast QPCR Device hardware and step-by-step instructions to system installation.
Software installation	Installation guide for application control software of the Ultrafast QPCR Device.
Operation introduction	Operation guide for the Ultrafast QPCR Device.
System maintenance	General system maintenance guide.
Fault diagnosis	Answers to common questions and troubleshooting methods.

Agreement

In the main text of this manual, the names of keys, buttons, and menu items are all marked with [ ]; the names of interfaces, etc. are marked with [ ]. For Example:

● [Main Interface] includes four main menu buttons: [Search], [Experiment], [Setting], and [Help].

How to get help

If you encounter any problems and need help during the installation and use of the Ultrafast PCR Device, please contact the technical support department of Baicare (Tianjin) Biotechnology Co., Ltd. in time. The contact information is as follows:

Company website: http://www.bai-care.com

Technical Support

Tel: 400-898-0905

Email: support@bai-care.com

Please prepare the following information:

● Product serial number of the Ultrafast QPCR Device (on the product label on the rear panel of the Device)

● Version number of the application control software

● Description of the problem phenomenon

● The methods and operating steps used by you to solve the problem

● Contact information such as your telephone, fax and email address

Important safety information

The operator of the Ultrafast QPCR Device should have read the manual or received appropriate training, understand how to operate the Device and software correctly, and know about all safety issues. In this manual, the so-called "user" refers to an operator who has read the manual or received appropriate training. Any operation beyond this manual is strictly prohibited.

Safety tips used in this manual

Please follow the safety precautions in this manual:

⚠	In all cases marked with this symbol, the accompanied documents must be consulted in order to clarify the nature of the potential hazards and the measures that must be taken.
⚠	Warning: If no precautions against the cautionary content or operation are taken, it may cause serious harm to the user or others.
⚠	Note: Failure to follow the prompts may result in Device damage, data loss or poor system performance.

Protective device cover

The Device cover subjected to protective design can prevent you from contacting the strong LED light and motion parts. During the general operation, you will not be exposed to the internal structure of the Ultrafast QPCR Device.

⚠	Warning: Do not open the protective cover of the Device or touch the inside of the Ultrafast QPCR Device in any other way. Opening the Device cover may cause damage to the internal parts of the Device, and encounter dangers such as strong LED light and motion parts.
⚠	Warning: In case that the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

There are high temperature parts and motion parts inside the Ultrafast QPCR Device that users will not touch. The back panel of the Ultrafast QPCR Device does not have an interlocking device, but is locked with screws. Please do not loosen any screws to open the back panel.

Dangerous high temperature

There are high-temperature parts inside the Ultrafast QPCR Device. Under normal operating conditions, the Device cover can protect the user from touching the high-temperature parts inside the Device.

	Warning:
	Do not try to touch the inside of the Ultrafast QPCR Device. Exposure to high temperature parts can cause serious injury.

Biological hazard

The test samples of the Ultrafast QPCR Device are biologically hazardous, and the samples to be tested and the chips after the test must be properly handled.

When there is a need to touch samples or use biological reagents during the use of the equipment, please wear or use the protective gloves of the corresponding level or take other protective measures in accordance with the instructions of the kit and the relevant regulations of laboratory biosafety operations.

If dangerous substances leak on the equipment surface or enter the inside of the equipment, immediately disconnect the power supply, wear protective gloves of the corresponding level, wipe it with 75% alcohol semi-dry wet cotton gauze or semi-dry wet lens tissue, and dry it naturally or blow it with hot air. After being dried, the Device can be used again.

	Warning:
	The detection samples of the Ultrafast QPCR Device must be operated and processed in accordance with the biological operation specifications, relevant laws and regulations, and the requirements of the local health department.

Motion parts

The motion parts inside the Ultrafast QPCR Device may also cause injury. Under normal operating conditions, the Device cover is designed to ensure that the user will not be injured by motion parts. The Device cover can ensure that the user will not touch the motion parts during the experiment.

	Warning:
	Except for the reagent tubes of the specifications defined in this manual, do not place any other items in the Device. The defined reagent tubes should be placed at the regulated position according to the specified operation
	Do not open the upper cover of the Device forcibly during the experiment.

	To ensure the normal operation of the Device, do not allow strong light (sunlight, spotlight, etc.) to enter the inside of the Device through the upper cover.

Product labeling
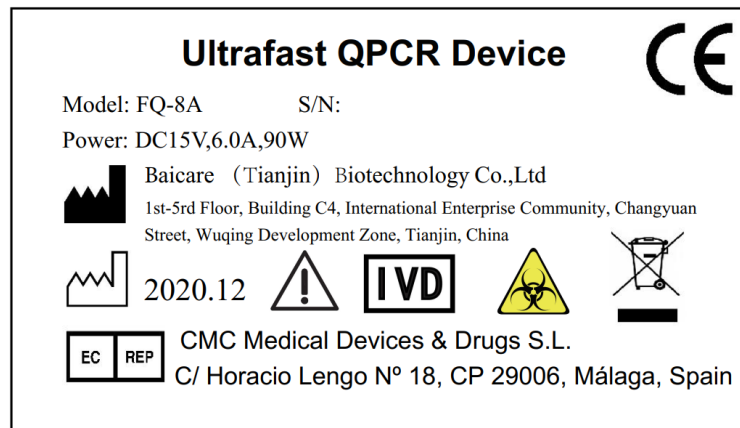
A product label is affixed onto the rear panel of the Ultrafast QPCR Device.

It is a warning sign, indicating the important warning information that the user needs to refer to the instructions for use.

It is a biological risk indicator, indicating that there is a potential biological risk related to medical devices.

It is an in vitro diagnostic medical device identifier, indicating that the medical device is an in vitro diagnostic medical device.

Chapter 1   System Overview

1.1 Basic principle

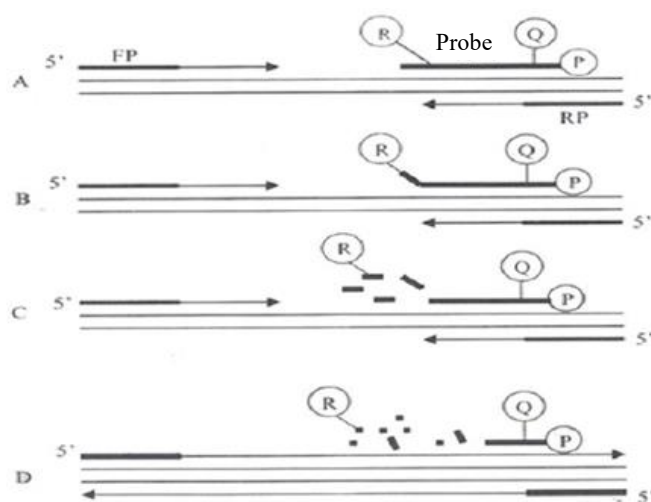The principle of fluorescent probe quantitative QPCR technology is used for this Device. This technology smartly combines nucleic acid amplification (PCR), hybridization and spectrum technology based on conventional QPCR by adding fluorescent labeled probes, to achieve the accurate quantitative detection of target genes. It is developing into a routine technique for clinical laboratory diagnosis.

The working principle of the fluorescent probe quantitative QPCR technology is to use the 5'→3' exonuclease activity of Taq enzyme to add a fluorescently labeled probe into the QPCR technology reaction system. The probe can specifically hybridize with the DNA template contained in the primer sequence. The 5' end of the probe is labeled with the fluorescent reporter group FAM, and the approaching 3' end is labeled with the fluorescence quenching group TAMRA. An energy delivery structure is formed between the two. When the probe remains intact, the fluorescent signal excited by the 5' end fluorescent reporter group is absorbed or suppressed by the 3' end quencher group, and there is no change in fluorescent signal. When the target gene exists in the QPCR reaction system, a specific nucleic acid fragment will be amplified, and the fluorescent probe will hybridize with it according to the principle of base pairing. When QPCR enters the extension (replication) phase, the Taq enzyme starts from the 3' end of the primer and moves along the DNA template with the extension of a new strand. When it moves to the probe binding position, its 5'→3' exonuclease activity acts and the probe is cut off (nick translation effect). The energy transfer structure between the fluorescent reporter group and the quencher group is destroyed, the quenching effect of the quencher group is relieved, and the fluorescent signal of the fluorescent reporter group is released (Figure 1). Each time when a specific nucleic acid fragment is replicated in the QPCR reaction, a probe is cut off, accompanied by the release of a fluorescent signal.   Since there is a one-to-one relationship between the number of released fluorescent groups and the QPCR product, the presence or strength of the fluorescence signal detected by the fluorescence detection technology represents the presence or quantity of the amplified product. The fluorescent signal is an effective and specific signal representing the amplified product, so there is no need to separate effective and invalid information, and real-time detection by the Device is realized, which creates conditions for the new QPCR quantitative principle.

Figure 1-1   Reaction Mode of Fluorescent Probe Quantitative QPCR

(A) Polymerization   (B) Strand displacement   (C) Cracking (D) Polymerization

(R: FAM; Q: TAMRA; FP: upstream primer; RP: downstream primer)

The extracted nucleic acid is added to the reagent tube, and the Device controls the temperature through the temperature to amplify the nucleic acid in the reagent tube. During the amplification process, a silicon photomultiplier tube is used to collect the fluorescent signal in real time. The light emitted by light source is focused on the reagent tube through the lens set and filter to induce the sample in the area to emit fluorescence. The fluorescence passes through the filter and convex lens successively to reach the detection area of the silicon photomultiplier tube, and transmits the signal to the control board. The software processes the signal, draws a real-time curve, and interprets the results after the detection is completed.

1.2 Main structure

The Ultrafast QPCR Device is mainly composed of motion parts, temperature control unit, main control unit, housing and analysis software. The motion parts are composed of lifting component, translation component, and scanning component; the scanning component is composed of optical module and scanning motion part, etc.; the optical module is composed of a transmitting unit, a lens and a receiving unit.
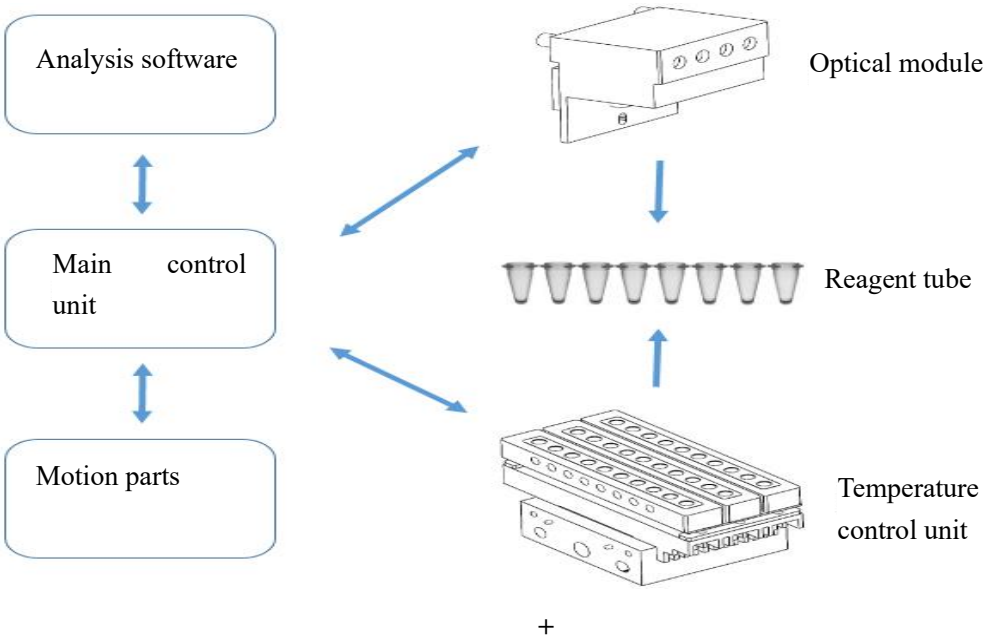
Figure 1-2 Device Structure Composition Diagram

1.3 Name and model

Table 1-1 Product Naming Rules

Product Name	Product Model

Ultrafast QPCR Device	FQ-8A

1.4 Applicable scope of the Device

The Ultrafast QPCR Device is used together with matching detection reagents based on real-time polymerase chain reaction (QPCR) technology. It is used clinically for qualitative detection of analytes from human samples, including viruses, bacteria, fungi and other pathogens and drug resistance genes.

Personnel who have read the product manual or received appropriate training can operate and use the product.

The Device can be reused, and its matching reagent tubes and reagents are only for one-time use.

1.5 Required materials and equipment

Table 1-2 Required Materials and Equipment

Description	Supplier	Quantity
Ultrafast QPCR Device and accompanied accessories	Baicare (Tianjin) Biotechnology Co., Ltd	1 set

1.6 Contraindication:

Not found yet

Chapter 2 Hardware Installation

2.1 Overview

The Ultrafast QPCR Device can be installed by users. Before starting to install the software and hardware, users should carefully read and understand the requirements and operating steps in this manual. Users should strictly follow the installation and operating steps in the manual to avoid damage to the Ultrafast QPCR Device.

2.2 Installation requirements

2.2.1 Environment

Environmental conditions for the use of the Ultrafast QPCR Device:

(1) Indoor/outdoor use: Indoor use;

(2) Altitude: The altitude does not exceed 2000m;

(3) Ambient temperature: The operating temperature is 15°C~30°C, and the ambient temperature change during operation does not exceed ±2°C;

(4) Ambient humidity: 20%~85%, relative humidity (non-condensing);

(5) Power supply voltage fluctuation: Not more than ±10% of the nominal voltage;

(6) Transient overvoltage category: II;

(7) Rated pollution degree: Pollution degree is level 2.

Category of Ultrafast QPCR Device equipment: Portable equipment.

Power supply of Ultrafast QPCR Device:

(1) Power voltage: Single-phase AC 220V AC;

(2) Frequency: 50Hz;

(3) Power input: 90VA.

Since the Ultrafast QPCR Device is a precision optical Device, it is necessary to ensure that the environment is clean. Please install the Ultrafast QPCR Device away from windows, ventilation pipes and near other facilities that may cause drastic changes in temperature and humidity. Do not place the equipment at the place where it is difficult to operate and disconnect the device, so as not to cut off the power supply of the Device in a sudden situation.

During the experiment, the Ultrafast QPCR Device will emit a certain amount of heat, so appropriate ventilation and air flow adjustment may be required in the room.

The sound pressure level of the Ultrafast QPCR Device meets the requirements of 12.5.1 in GB 4793.1-2007/IEC 61010-2001. At the operator's normal working position, and at a distance of 1m from the equipment that produces the highest sound pressure level, the measured pressure level of sound

produced by the equipment does not exceed 65dB(A).

	Warning: Do not place objects around the front and rear panels of the Device to avoid turning off the power supply of the device or loosening the power cable in an accidental situation.

2.2.2   Space

The sizes of the Ultrafast QPCR Device are 283mm (length) × 192mm (width) × 120mm (height), and the workbench of the Ultrafast QPCR Device must be able to bear a weight of at least 4kg.

2.2.3   Mains

The Ultrafast QPCR Device uses AC 220V, 50Hz power supply, and the overall maximum power consumption is about 90 VA.

2.3 Acceptance inspection

2.3.1   Initial inspection

If you find any visual damage, please indicate the damage on the receipt when you sign for the system. If you find any internal damage or concealed damage after opening the package, please contact the delivery agent and Baicare (Tianjin) Biotechnology Co., Ltd. at the same time.

	Note: If you find any obvious damage on the system, do not connect it to a power source.

2.3.2   Open the package

	Note: Care must be taken when opening the packaging box and placing the equipment on the workbench, because vibration and collision can cause internal damage to the Ultrafast QPCR Device or displacement of optical components.

2.4 Hardware introduction

2.4.1 Front
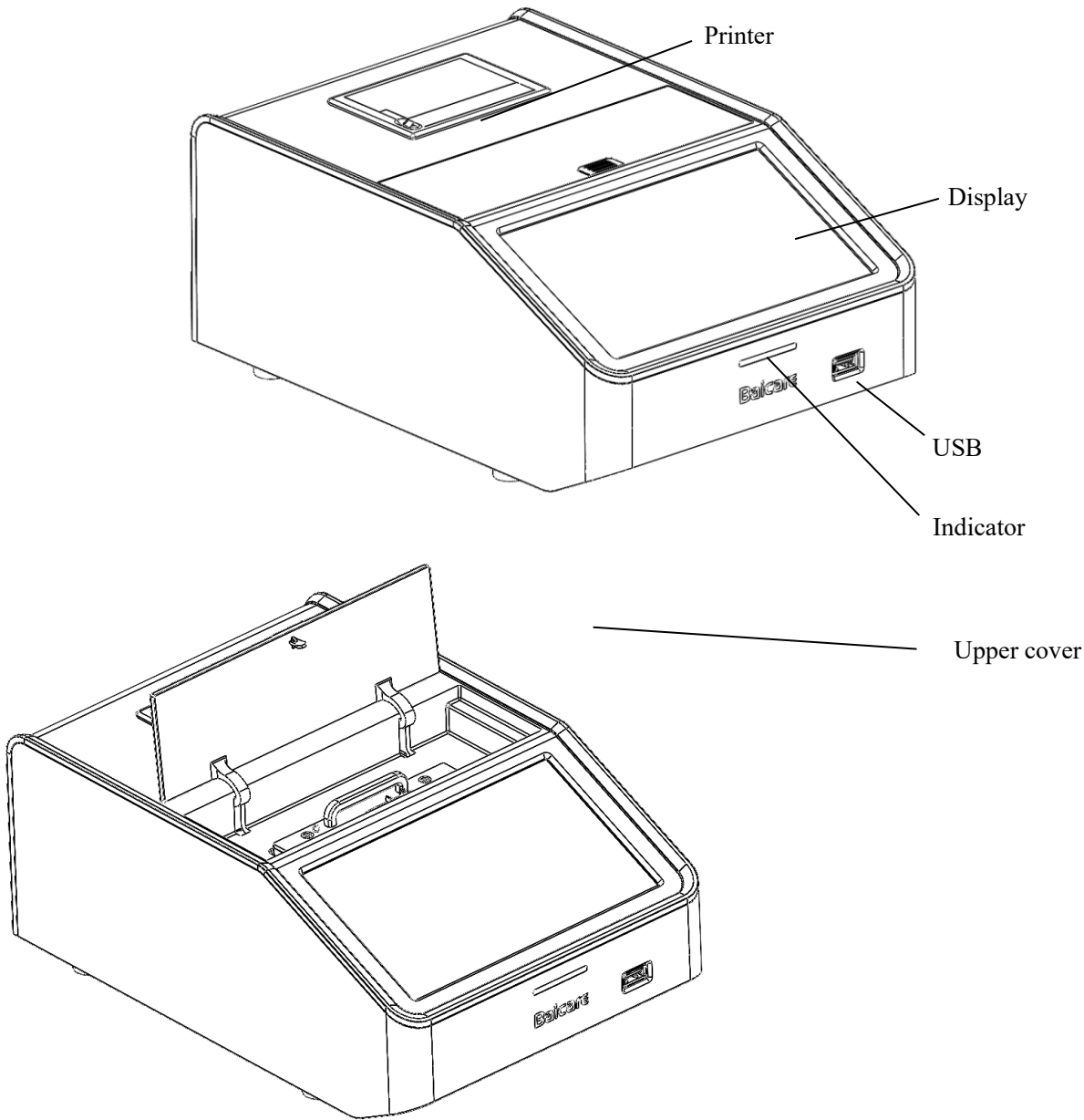
Figure 2-1   Front of the Device

The blue indicator light indicates the standby state; the green indicates the running state; the red indicates the fault state.

	Note:
⚠️	Please do not put anything other than the reagent tubes specified in the manual into the Device.
	Do not open the upper cover of the Device forcibly during the experiment.

2.4.2   Rear
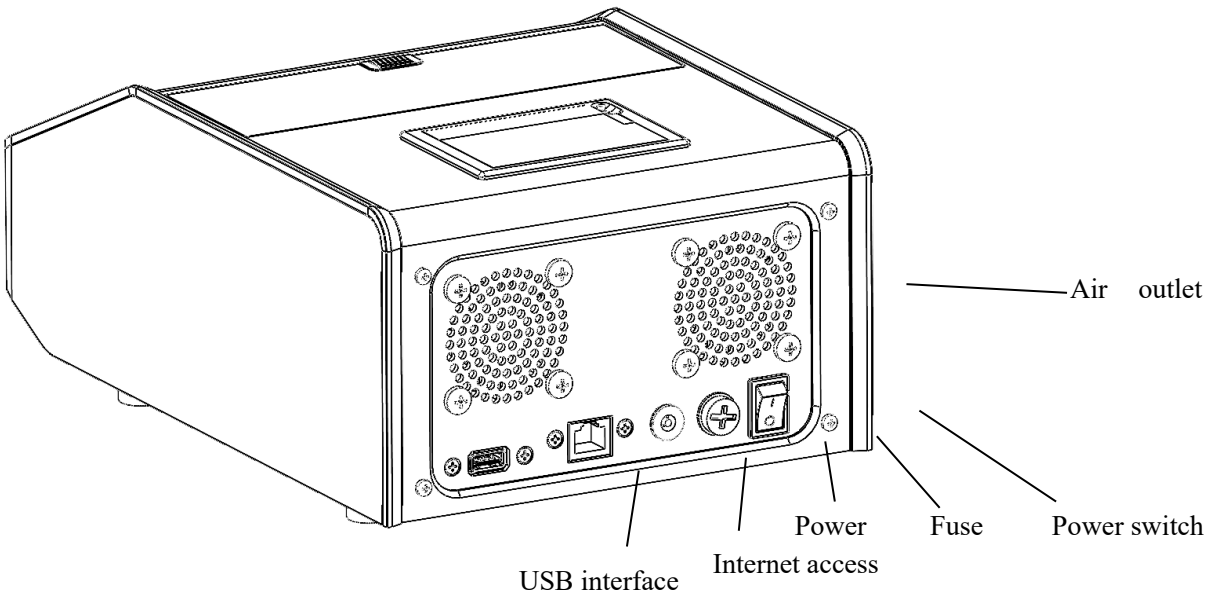
Figure 2-2 Rear of the Device

⚠	Note: Do not cover the air outlet or insert any objects.

2.4.3   Cable lines

Figure 2-3   Power Line   Figure 2-4   Adapter

⚠	Note: Please use the fuse, power line and power adapter configured according to the factory standard. Any parts of the Device can only be inspected or provided by the manufacturer or its agency.

2.5 Installation

Step 1

Place the Ultrafast QPCR Device on a level and stable workbench, and the power switch of the Device needs to be turned off.

Step 2

Connect the power adapter cable to the power socket of the Device, and connect one end of the power line to the socket of the power adapter and the other end to the indoor electrical socket.

⚠	Note: Ensure that the power supply system has an independent ground wire; otherwise it may cause electric shock.

2.6 Start the system

Step 1

Turn on the power switch of the Device to start the Device.

Step 2

After the Device is in the ready state, perform the preparatory work before the experiment and wait for the experiment.

2.7 Use method

Step 1: The sample to be tested is added to the applicable reagent tube and the tube cap is closed tightly, and then the tube is loaded into the reagent tube rack, as shown in the figure.
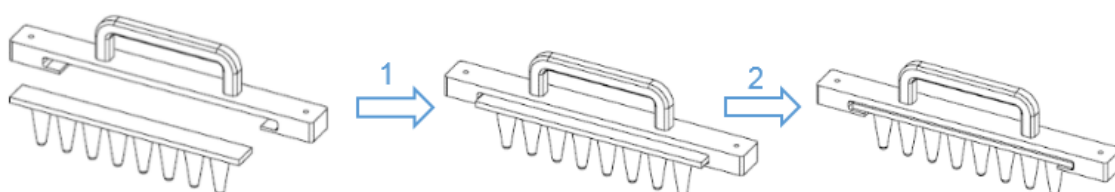
Figure 2-5   Physical Renderings after Installation

Step 2: Put the reagent tube rack into the Device vertically.

Figure 2-6   Direction Confirmation

Figure 2-7   The Effect after Putting it in the Reaction Tank

Step 3: Close the upper cover of the Device, set relevant parameters, and then start the test.

2.8 Shut down the system

Turn off the switch button of the Device and disconnect the power supply.

2.9 Status description of indicator light

Indicator light	Status	Instruction
Blue	Flashing	The heating tank is working
	Always bright	Standby mode
Green	Always bright	In experiment
Red	Always bright	Equipment failure

Chapter 3   Operation Introduction

3.1 Overview

This chapter mainly explains the operation introduction of this system, including: system startup, software interface introduction and so on. It is suggested that you read this chapter carefully before using the Device. If you have already mastered the content introduced in this chapter, you can go directly to the next chapter.

3.2 Start the system

Turn on the power switch of the Device and the system will start automatically.

3.3 Interface description

This section will introduce each interface of the system software respectively. It is recommended that you read this section in detail. The software version introduced in this chapter is V1.0.0.

3.3.1   Startup interface

After the system starts, first load [Startup Interface], as shown in Figure 3-1.

Figure 3-1   Startup Interface

[Startup Interface] After loading, it will enter [Self-Check Interface], and the Device will start self-checking. Check the four modules of communication, motion, fluorescence, and temperature in sequence, as shown in Figure 3-2.
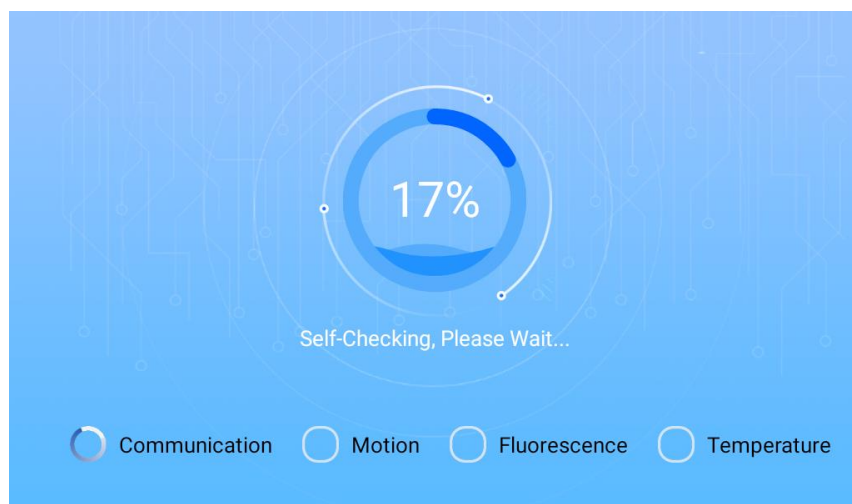
Figure 3-2   Device self-check interface

If the self-check is accepted, the system will enter the main interface. If the self-check failed, two buttons of [Recheck] and [Skip] will be displayed, and the failed module will turn into a red prompt, as shown in Figure 3-3. Click [Recheck] and the Device will perform self-checking again, and click [Skip] to enter [Main Interface]. Note: The experiment operation cannot be carried out if the self-check failed.
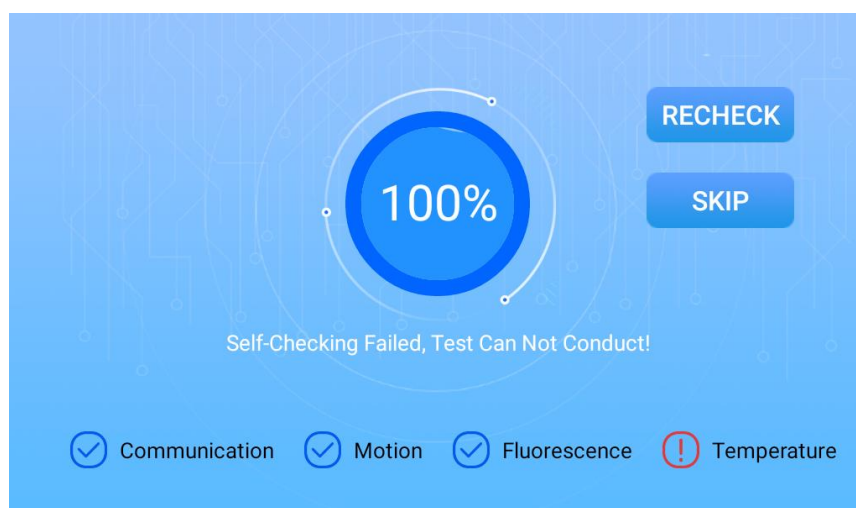
Figure 3-3   Self-check Failed Interface

3.3.2   Main interface

After all self-checks are accepted, it will automatically enter the [Main Interface], as shown in Figure 3-4.

Figure 3-4   Main Interface

[Main Interface] includes four main menu buttons: [Search], [Experiment], [Setting], and [Help].

[Search] Used to inquire historical experiment records. It can be inquired by date or number.

[Experiment] Start a new experiment or return to an ongoing experiment.

[Setting] Contain experimental item settings, process settings, and system settings that require login permissions.

[Help]   Pictures and texts introduce the help of the Device.

3.4   Query menu

Click the [Query] menu button on the [Main Interface] to enter the [Query Type Interface], as shown in Figure 3-5.

Figure 3-5   Query type interface

As shown above, the query type can be inquired by [Date] or [Sample Name].

3.4.1 Search by date

Click [Query Type Interface] Date submenu item to enter [Search by Date Interface], as shown in Figure 3-6. You can select a fixed time period [Today], [Recent Week], [Recent Month] to inquire data, or select [Custom] to manually select a time period for query.

Figure 3-6   Search by Date Interface

As shown above, click to select any query type in the [Query Type Interface], and the system will retrieve the experimental data corresponding to the time period, and the results of the retrieved data will be displayed in the [Query List Interface], as shown in Section 3.4.2 for details.

3.4.2 Search sample

Click [Query Type Interface] Date submenu item to enter [Search Sample Interface], as shown in Figure 3-7.

Figure 3-7   Search Sample Interface

As shown above, enter the sample number in the [Search Sample Interface] and click the [OK] button, and the system will retrieve the experimental data according to the input content; if you do not enter anything, click the [OK] button, and the system will retrieve all the experimental data. The results of the retrieved data are displayed in [Search List Interface], as shown in Section 3.4.3 for details.

3.4.3   Query list

The experimental data retrieved by date query or sample query will be displayed in the [Query List Interface], as shown in Figure 3-8.

Figure 3-8   Query List Interface

As shown above, in the [Query List Interface], all experimental data that meets the query conditions are displayed, which can be loaded by sliding up and down. At the same time, the system provides the function menus batch export and delete. Select the check box in front of the data, and then click [Delete] button to delete data in batches; click the [Export] button to package and export the data to U disk/FAST content.

Click on a certain item of data in the data list to enter [Query Analysis Interface], as shown in Section 3.4.4 for details.

3.4.4   Query analysis

In the [Query List Interface], click the data to be analyzed, and enter the [Query Analysis Interface], as shown in Figure 3-9
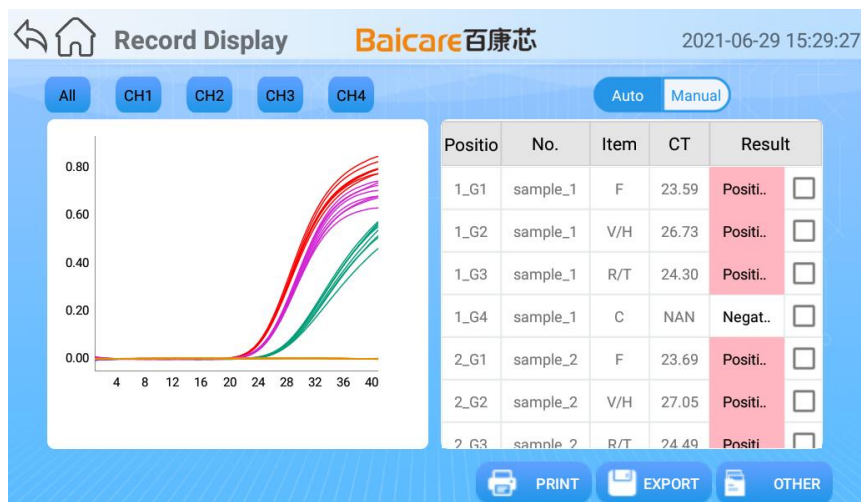
Figure 3-9   Query Analysis Interface

1)   The [Query Analysis Interface] displays the curve and result list. If there are quantitative items, there will be a standard curve interface.

2)   CH1/CH2/CH3/CH4 check button can be clicked to dynamically update the curve and result list.

3)   The second-order derivative algorithm is used to process the data by default. If the algorithm setting is selected as interpolation. The threshold window is displayed under the curve area. Select a single channel, and the threshold can be changed (the multi-select channel threshold input box is not available). The curve and result will change accordingly based on the threshold.

4)   The results on the result column in the result list can be changed. Select a row of results and the corresponding curve will be highlighted.

5)   On the [Query Analysis Interface] click [Other] and select [Sample Settings] to enter [Sample Type Setting Interface], and you can modify the sample, as shown in Figure 3-10.

Figure 3-10   Results Analysis Interface

[Query Analysis Interface] detailed functions and usages are shown in Table 3-1.

Table 3-1 Introduction to Query Analysis Interface Function

No.	Name	Type	Function
1	Select All\CH1-4	Button	Control whether the four channels of the fluorescence curve are displayed or not
2	Second order derivative\interpolation	Single choice	Data analysis algorithm selection
3	Print	Button	Print test results
4	Export results	Button	Export test results to U disk
5	Other>Rename	Control	Rename test data
	Other>Sample settings	Button	Enter [Sample Type Setting Interface] to set sample information
	Other>Original data export	Button	The original fluorescence data and CT data are compressed as a zip file and exported to U disk
	Other>Item information	Button	View the item information of the experiment
	Other>Send HL7 report	Button	The test data are sent to the configured server through the HL7 protocol

3.5 Experiment menu

Click the [Experiment] menu button on the [Main Interface] to enter the [Experiment Setting Interface], as shown in Figure 3-11. This section will introduce the experimental operation steps in detail, and you are suggested to read them in detail.
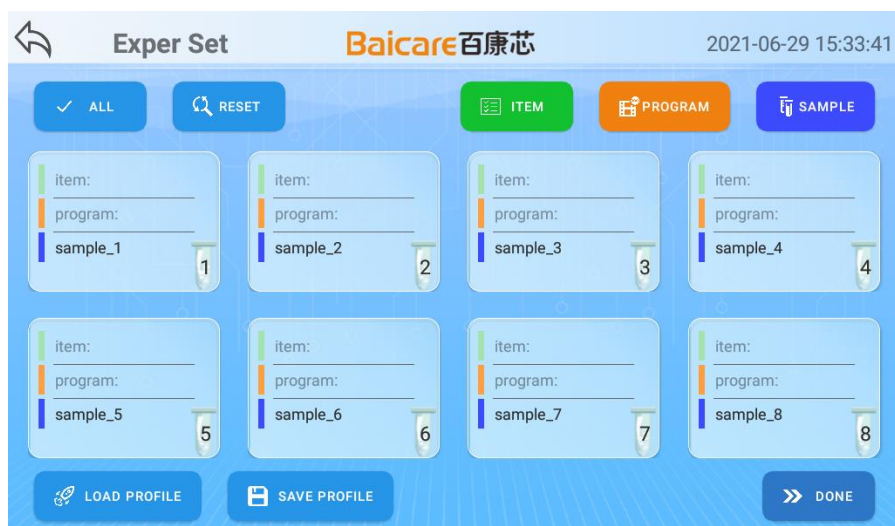
Figure 3-11   Experiment Setting Interface

[Experiment Setting Interface] contains 8 hole position information cards and 8 function buttons. Click 1-8 cards in the interface to select the hole position that needs to be set.

[Hole Position Card]: The card number corresponds to the reaction tank of the Device one to one, and each hole position card is identified with a different color to indicate the set item information, process information, and sample type. The sample type is the sample to be tested by default.

[Select All]: Select all hole cards

[Reset]: Clear the experiment information currently set, and you can select and set again.

[Item]: To set up experimental items for the selected hole position, you need to select the hole position first.

[Program]: Set up the process information of the experiment.

[Sample]: To set the sample type for the selected hole position, you need to select the hole position first.

[Save Profile]: Save the current experiment settings as a plan for quick settings in the next experiment.

[Load Profile]: Select a saved profile and the system will automatically perform quick settings.

3.5.1   Set up experimental items

1)   In the [Experiment Setting Interface], select the hole position card that needs to be set, as shown in Figure 3-12, and select the hole positions 1, 2, 7, and 8.
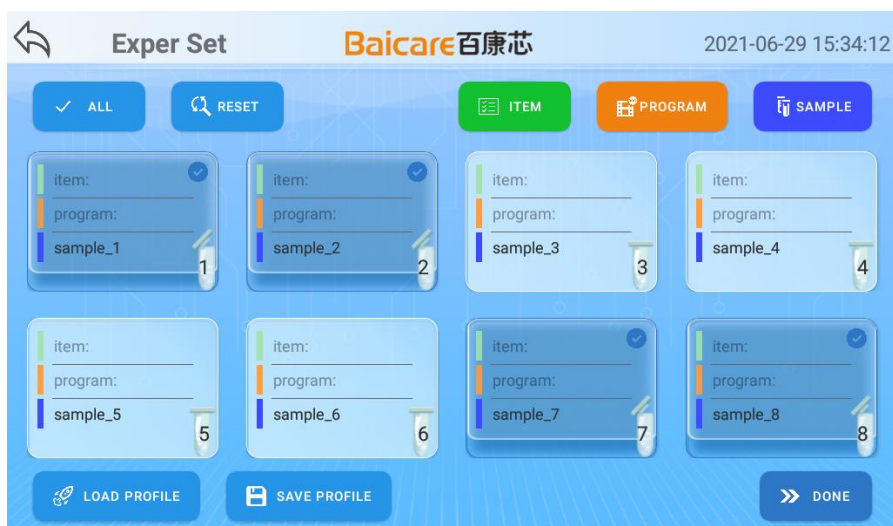
Figure 3-12 Select the Hole Position in the Experiment Setting Interface

2) Set up experimental items

After selecting the hole position, click the [Item] button to enter the [Test Item Selection Interface], as shown in Figure 3-13.

Figure 3-13　Test Item Selection Interface

You can slide up and down to display the name list of all the test items in the [Test Item Selection Interface], and the system defaults to select the first item; you can also click to select other items. After selecting the item, click [OK] button to return to the [Experiment Setting Interface] and display the selected item name on the corresponding hole position card, as shown in Figure 3-14.
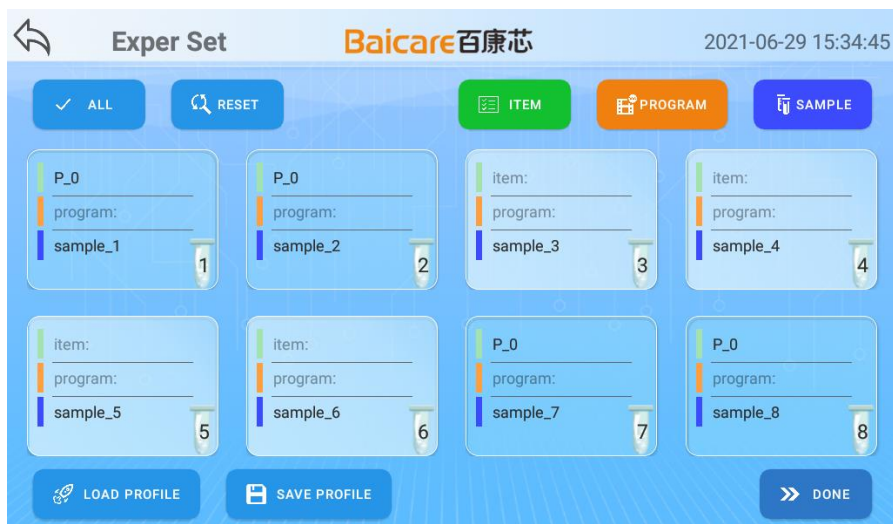
Figure 3-14   The hole positions 1, 2, 7, 8 on the Experiment Setting Interface have been selected items

3)   Manage experimental items

You can also manage items in the [Test Item Selection Interface], including adding, deleting, and editing and modification. Taking editing as an example, select the item to be modified in the [Test Item Selection Interface], and then click [Edit] button to enter the item editing interface as shown in Figure 3-15.

Figure 3-15   Item Edit Interface

[Qualitative] | [Quantitative] option button: The setting item is a quantitative or qualitative test item.

[Name]: The name of the item can be modified.

[Sub Item]: As there is a need to detect the fluorescence channel, set whether to detect the channel by checking or canceling the check box in front of the channel.

[OK]: Save the current modified settings and return to the previous interface.

[Back]: Do not save this modification, and return to the previous interface.

4) Precautions

    a.   In the [Experiment Setting Interface], different items can be set for varying hole positions. However, there can only be one quantitative item for a test. If multiple quantitative items are set, the system will prompt modification.

    b.   In the [Experiment Setting Interface], you need to select the hole position card before clicking the [Item] button. If you do not select it, the system will select all holes by default.

3.5.2   Set up the experiment process

1)   In the [Experiment Setting Interface], click the [Program] button to enter the [Program Selection Interface], as shown in Figure 3-16.

Figure 3-16   Program Selection Interface

    In the [Program Selection Interface], the name list of all test processes is displayed by sliding up and down. The system selects the first process by default, or you can click to select other processes. After selecting, click the [OK] button to return to the [Experiment Settings Interface] and the selected process name is displayed on the corresponding hole position card, as shown in Figure 3-17.
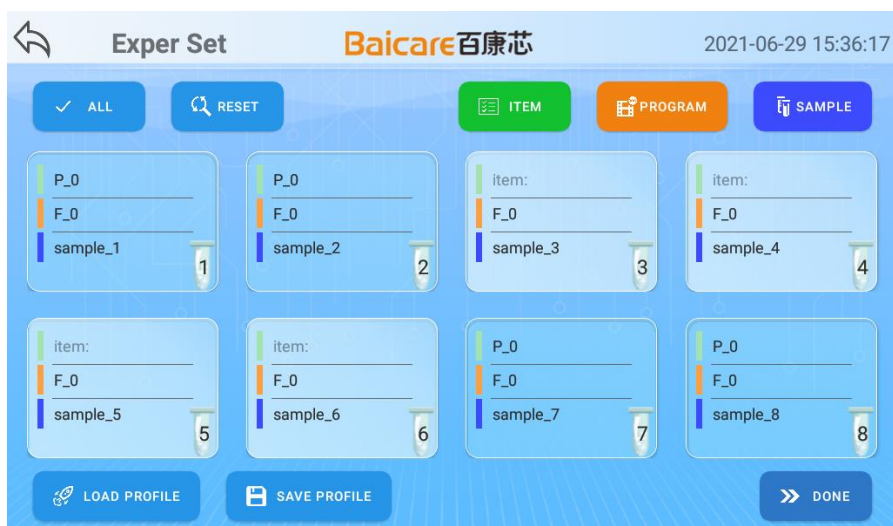
Figure 3-17   The program has been selected on the experiment setting interface

3)   Manage the experiment program

In the [Program Selection Interface], the program can also be managed, including adding, deleting, editing and modifying. Take editing and modification as an example, select the process to be modified in the [Program Selection Interface], and then click the [Edit] button to enter the [Program Editing interface], as shown in Figure 3-18
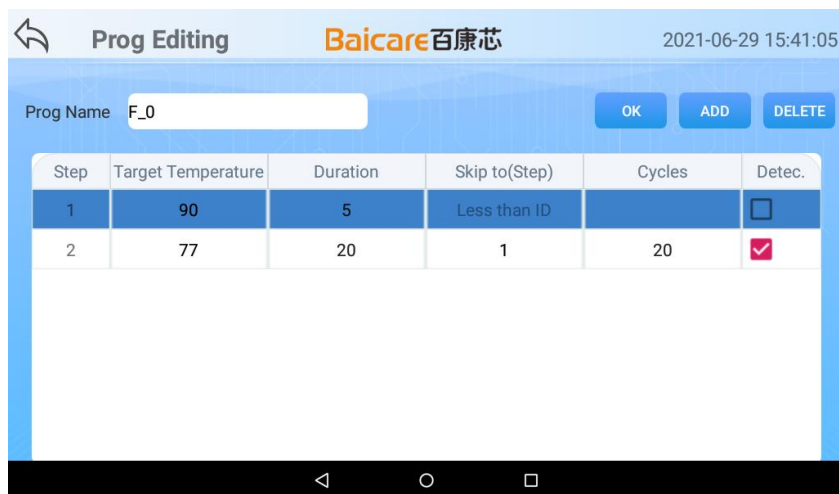
Figure 3-18 Program Editing Interface

You can set multiple program steps on the [Program Editing Interface], and these steps will be automatically executed according to the step number sequence, jump step and cycle number during test.

[Program Name]: You can enter the program name.

[Add]: Add a process step.

[Delete]: Delete the selected process step.

[OK]: Save the current modified settings and return to the previous interface.

[Back]: Do not save this modification, and return to the previous interface.

[Step]: Number of each step.

[Target Temperature]: The temperature value that this step needs to reach.

[Duration]: The time required to keep the target temperature.

[Skip to (Step)]: Steps that need to be skipped after the current step duration ends need to be set at the same time as the cycle number.

[Cycles]: Set the cycle number executed by skip.

[Detection]: After the duration of this step is over, whether fluorescence detection is required.

3) Precautions

　　a.　　Only one process can be set for each experiment, and there is no need to select the hole position card before setting the process in the [Test Setting Interface].

　　b.　　In the [Program Editing Interface] there are verifications for input items such as temperature value, skip step and cycles, and the details are subject to the system prompts.

3.5.3 Set sample type

1)　Select a hole position card in the [Experiment Setting Interface], and then click the [Sample] button to pop up the [Sample Type Setting Interface] to set the sample type of the hole position, as shown in Figure 3-19.
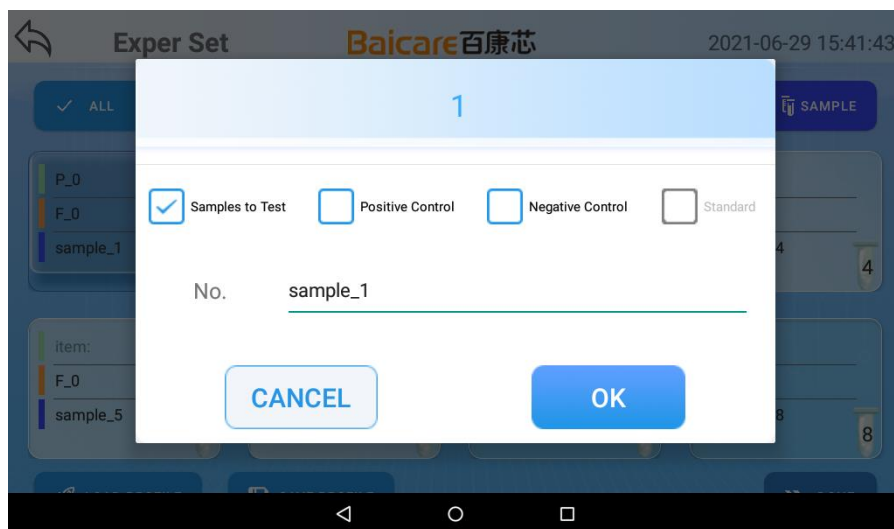
Figure 3-19 Sample Type Setting

[Sample Type Setting Interface] includes the selected hole position number, four sample types radio button, cancel and confirm buttons and other information.

[Sample to Test], set the hole position as the sample to be tested, and you can enter the sample name.

[Positive Control], set this hole position as a positive control, and you can enter the standard

concentration.

[Negative control], set this hole position as a negative control, and you can enter the standard concentration.

[Standard],set the hole position as a standard product, and you can enter the standard product concentration. Available for quantitative items.

[Cancel], cancel the setting and close the pop-up box.

[OK], save the settings and close the pop-up box.

2) Precautions

    a.   You need to set up the item and program before setting the sample type.

    b.   Before setting the sample type, you need to select only one hole position card.

    c.   For non-quantitative items, the sample type cannot be set as standard.

3.5.4 Experimental plan

To start a round of experiments, you need to set the item, process, and sample type for the hole position in the [Experiment Setting Interface] for routine operations. If the item, program, sample type and other parameters used in each experiment are the same, the above operations can also be simplified: Save the parameters of this experiment as a plan, select the profile directly for the next experiment, and the system will automatically set the experimental parameters.

1) Save Profile

In the [Experiment Settings Interface], click [Save Profile], enter the profile name in the pop-up box, and then click the [OK] button to save the set experimental parameters. As shown in Figure 3-20.
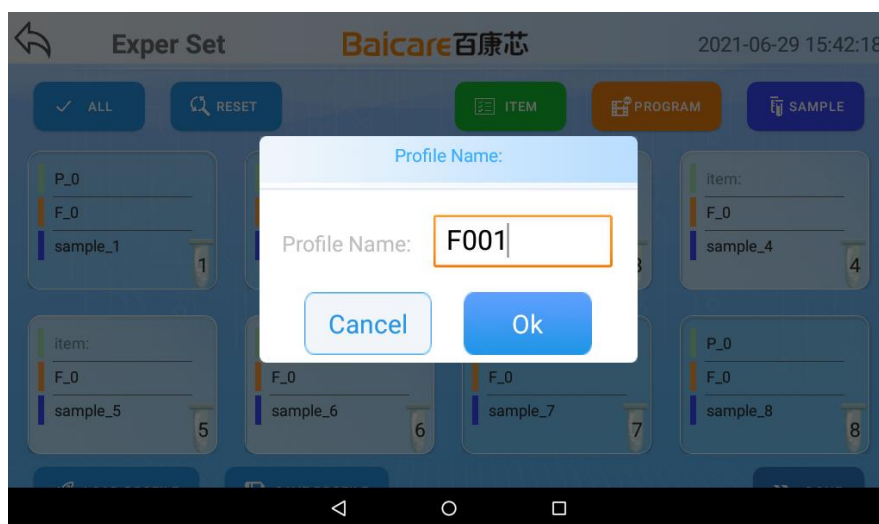
Figure 3-20 Save Profile Pop-up Box

2) Usage Profile

In the next experiment, click the [Load Profile] button in the [Experiment Settings Interface] to enter the [Select Profile Interface], as shown in Figure 3-21.

Figure 3-21 Select Profile Interface

[Select Profile Interface] displays a list of all profile names by sliding up and down. The system selects the first plan by default, or you can click to select other plans. After selecting, click the [OK] button to return to the [Experiment Settings Interface] and display the item, process, sample type and other information saved in the plan on the corresponding hole position card.

3.5.5 Experiment run

After setting up the item, process, and sample type in the [Experiment Setting Interface] through routine operations or loading a plan. Click the [Finish] button to complete the experiment setting operation and enter the [Experiment Information Interface], as shown in Figure 3-22.
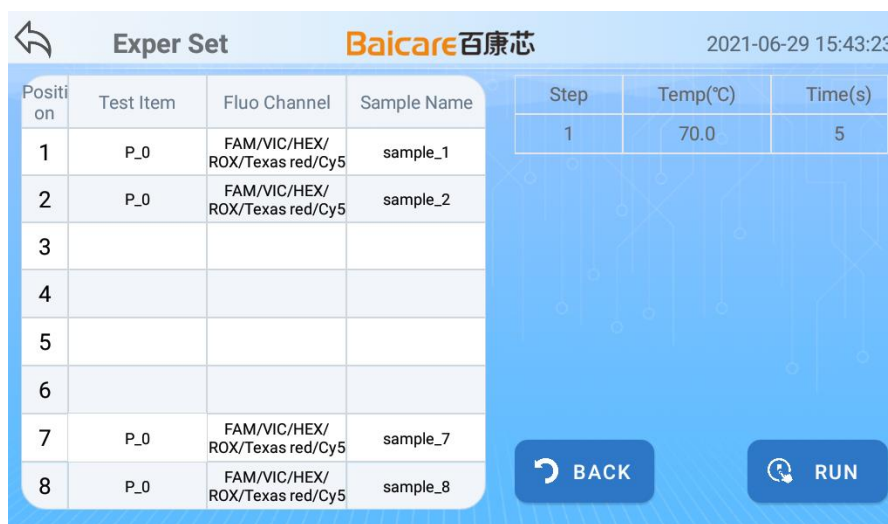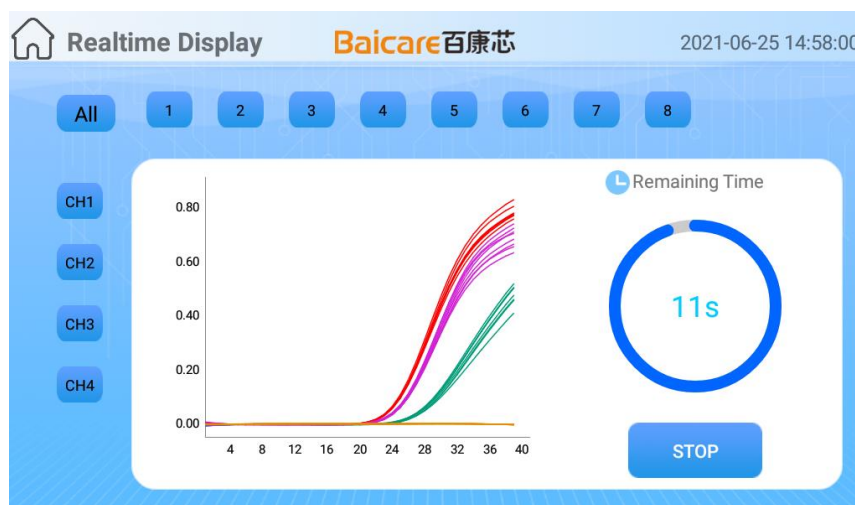

Figure 3-22 Experiment Information Interface

The [Experiment Information Interface] displays the item, sample type information and process

information of each hole position. Click the [Back] button to return to the previous interface for modification, click [Run] to enter [Realtime Display Interface] as shown in Figure 3-23, and start testing.

Figure 3-23 Realtime Display Interface

1)　The [Realtime Display Interface] displays the fluorescence curve of the selected channel and hole position in a realtime dynamic manner.

2)　Four fluorescence channels CH1, CH2, CH3 and CH4, and hole positions 1, 2, 3, 4, 5, 6, 7 and 8 all support check, and the curve area is dynamically updated according to the selected channel and hole position.

3)　Click the [Stop] button to end this experiment in advance and analyze the existing data (The experiment has not been completed, and the results can be judged artificially. In order to shorten the time, the experiment can be ended in advance). This operation is irreversible, please choose carefully.

4)　The remaining test time is calculated based on the dynamic estimation of the experiment.

3.5.6　Analysis of results

After the countdown of the [Realtime Display Interface] ends or the experiment is manually stopped, the system enters the [Result Analysis Interface], as shown in Figure 3-24.
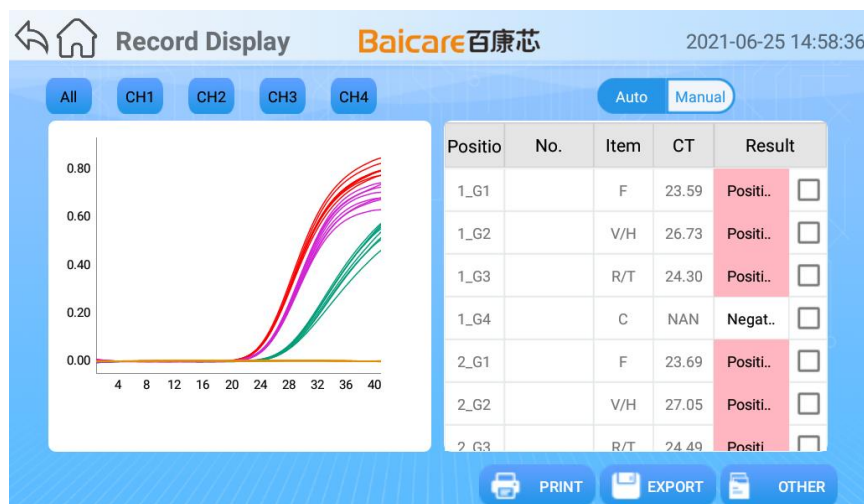
Figure 3-24   Results Analysis Interface

1)   The [Result Analysis Interface] displays the curve and result list. If there are quantitative items, there will be a standard curve interface.

2)   CH1/CH2/CH3/CH4 check button can be clicked to dynamically update the curve and result list.

3)   The second-order derivative algorithm is used to process the data by default. If the algorithm setting is selected as interpolation, the threshold window is displayed under the curve area, select a single channel, and the threshold can be changed (the multi-select channel threshold input box is not available). The curve and result will change accordingly based on the threshold.

4)   The results on the result column in the result list can be changed. Select a row of results and the corresponding curve will be highlighted.

5)   In the [Result Analysis Interface], click [Other] and select [Sample Settings] to enter [Sample Type Setting Interface], where you can modify the sample, as shown in Figure 3-25.

Figure 3-25　Results Analysis Interface

The detailed functions and usages of the [Result Analysis Interface] are shown in Table 3-2.

Table 3-2 Introduction to Result Analysis Interface Functions

No.	Name	Type	Function
1	Select All\CH1-4	Button	Control whether the four channels of the fluorescence curve are displayed or not
2	Second order derivative\interpolation	Single choice	Data analysis algorithm selection
3	Print	Button	Print test results
4	Export results	Button	Export test results to U disk
5	Other>Rename	Control	Rename test data
	Other>Sample settings	Button	Enter [Sample Type Setting Interface] to set sample information
	Others>Original data export	Button	The original fluorescence data and CT data are compressed as a zip file and exported to U disk
	Others>Item information	Button	View the item information of the experiment
	Others>Send HL7 report	Button	The test data is sent to the configured server through the HL7 protocol

3.6　Setting menu

Click the [Setting] button in the [Main Interface] to enter the [Setting], where various settings of the software can be made.

The [Setting] is divided into two screens, and you can slide the screen left or right to switch between different screens. The first screen, as shown in Figure 3-26, contains two function menus [Program Setting] and [Test Item]; the second screen, as shown in Figure 3-27, contains 6 function

menus, namely device information, brightness, volume, algorithm, administrator mode, and maintenance mode.

Figure 3-26   Set the First Screen

Figure 3-27   Set the Second Screen

3.6.1   Program settings

Click the [Program Setting] button in [Setting], as shown in Figure 3-28, where you can set the experimental process, including the operations such as adding, editing, and deleting.

Figure 3-28   Process Setting Interface
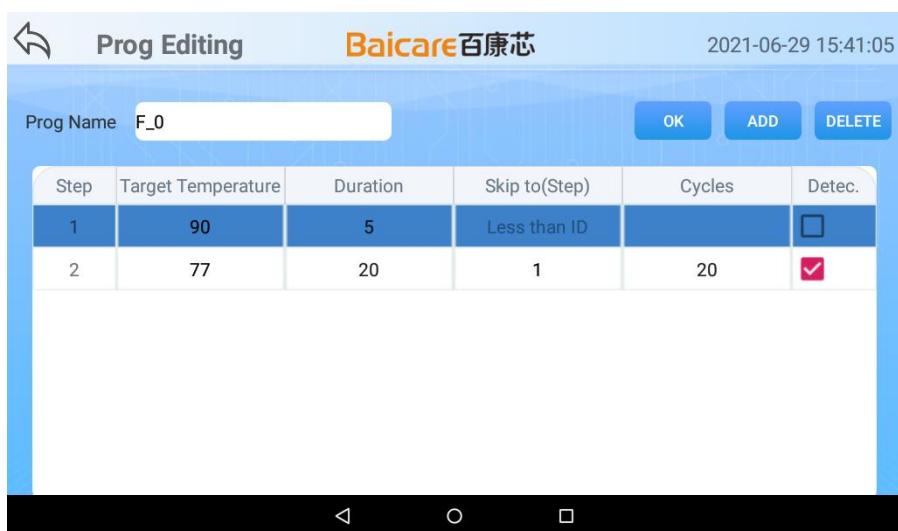
Figure 3-29   Process Editing Interface

3.6.2   Test item

Click the [Test Item] button in [Setting], as shown in Figure 3-30, and you can set the experiment program, including the operations such as add, edit, and delete.

Figure 3-30   Test Item Interface

Figure 3-31   Test Item Editing Interface

3.6.3   Device information

As shown in Figure 3-32, it displays the current product model, device number, software and hardware version and other information.

Figure 3-32 Device Information Interface

3.6.4   Brightness

As shown in Figure 3-33, you can adjust the brightness value of the current screen.

Figure 3-33 Brightness setting

3.6.5   Volume

As shown in Figure 3-34, you can adjust the volume value.

Figure 3-34   Volume Setting

3.6.6   Algorithm setting

As shown in Figure 3-35, you can select the fluorescence curve algorithm, and the second-order derivative system will automatically calculate the CT value; the interpolation algorithm selected can be calculated according to the set threshold of each channel.

Figure 3-35 Algorithm Setting

3.6.7   Administrator mode

[Administrator Mode] needs to be used by the customer's software system administrator. [Administrator Mode] interface is displayed on multiple screens, and each screen has several function buttons. Slide the screen left or right to switch between different screens. The function menu contains the settings of important system parameters.   The user name and password are required to log in. As shown in Figure 3-36.
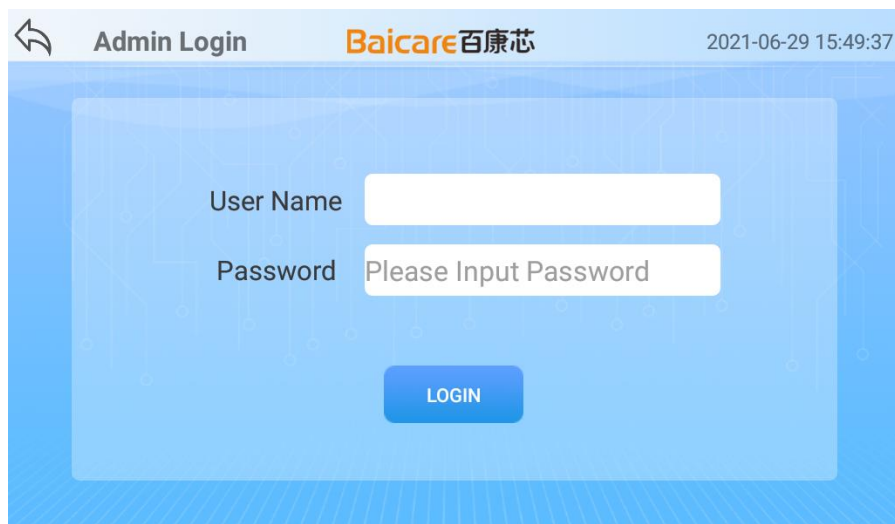
Figure 3-36 Administrator Login Interface

3.6.7.1   Administrator Screen 1

As shown in Figure 3-37, the administrator screen 1 contains 6 function menus, namely device number setting, network setting, server setting, datetime setting, self check and temperature block setting, etc.

Figure 3-37   Administrator Screen 1 Interface

The detailed button functions of [Administrator Screen 1] are shown in Table 3-3.

Table 3-3 [Administrator Screen 1] Button Function

No.	Name	Type	Function
1	Number settings	Button	Set the Device number

2	Network settings	Button	Set wireless network
3	Server settings	Button	Configure server information
4	Date and time	Button	Set Device time and date
5	Self-check	Button	Manual self-check
6	Temperature block setting		Configure the temperature values of three temperature tanks

3.6.7.2   Administrator Screen 2

As shown in Figure 3-38, the administrator Screen 1 contains 6 functional menus, namely PC switching, password change, software upgrade, firmware upgrade, log export, and stop application.

Figure 3-38   Administrator Screen 2 Interface

The detailed button functions of [Administrator Screen 2] are shown in Table 3-4.

Table 3-4 [Administrator Screen 2] Button Function

No.	Name	Type	Function

1	PC Switching	Button	Cooperate with the switching function of PC software
2	Password change	Button	Change the password of the current administrator
3	Software upgrade	Button	Upgrade software version
4	Firmware upgrade	Button	Upgrade firmware version
5	Log export	Button	Export log file to U disk
6	Stop application		Close the software and return to the desktop

3.6.7.3 Administrator Screen 3

As shown in Figure 3-39, the administrator screen 1 contains two function menus: temperature test and fluorescence test

Figure 3-39   Administrator Screen 3 Interface

The detailed button functions of [Administrator Screen 3] are shown in Table 3-5.

**Table 3-5 [Administrator Screen 3] button function**

No.	Name	Type	Function
1	Temperature test	Button	Perform temperature test of the setting program
2	Fluorescence test	Button	Perform fluorescence test of the selected program

3.6.8　　Operation and maintenance mode

The [Operation and Maintenance Mode] is only for the maintenance personnel of Baicare system. Under normal circumstances, customers do not need to enter.

3.7　Help menu

Click the [Help] button of [Main Interface] to enter [Help Interface], as shown in Figure 3-40.
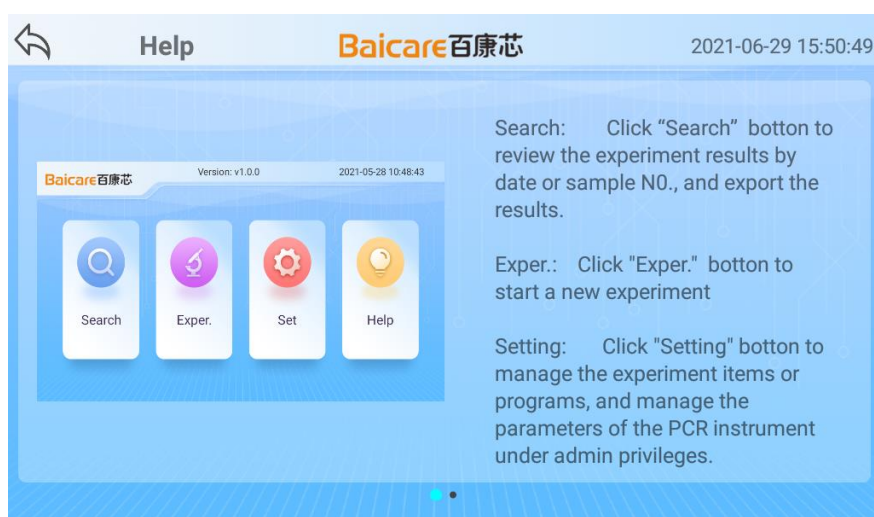
Figure 3-40　　Help Interface

The [Help Interface] introduces the help for the main functions of the Device in the form of graphics and texts. You can slide the screen left or right to view different pages.

Chapter 4   Quick Application Guide

4.1 Overview

On the basis of your understanding of the software interface (see 4.3 interface description for details), the following guide can guide you to quickly grasp the basic functions of the software. If you need to learn more about relevant content, please refer to the corresponding chapters above.

4.2 Operation procedure

Step 1

Turn on the Device and wait for the system to start. After starting, the system will automatically enter the [Main Interface].

Step 2

Click the [Experiment] menu in the [Main Interface] to enter [Experiment Setting Interface].

Step 3

Set the experiment information such as the item, program, sample type of the hole position, and click the [Finish] button to enter the [Experiment Information Interface].

Step 4

In the [Experiment Information Interface], click the [Run] button to enter the [Realtime Display Interface] to start the experiment.

Step 5

During the test program, check the experiment progress and realtime curve.

Step 6

To stop the test, click the [Stop] button on the interface, and the test will stop immediately.

Step 7

After the test is completed, the system will automatically enter the [Result Analysis Interface], where you can view the reaction process curve and test results.

Chapter 5　　Fault Diagnosis

5.1　Overview

This chapter provides reference suggestions and basic solutions for some problems that users may encounter during the use of Ultrafast QPCR Device. If these methods cannot solve your problems, please contact our company's technical support department.

5.2　Problems and solutions

5.2.1　　The device cannot be started

Restart the Device after disconnecting the power supply. If the problem still occurs, please contact technical support personnel for processing.

5.2.2　　Re-enter the main interface after the interface flashes

This problem is that the system software automatically returns to the interface when it is in trouble. If the problem continues to occur, please contact technical support personnel for processing.

Appendix 1   Specification details

Specifications	Description
Specification of reaction tube	Adapt to QPCR 8-strip tube (100ul)
Fluorescent dye	4 (FAM, VIC(JOE) , ROX, Cy5)
Optical system	LED + APD
Temperature range	30℃—100℃
Heating rate	Average heating rate: From 50℃~90℃, it should not be less than 1.5℃/s Maximum heating rate: From 50℃~90℃, it should not be less than 2.5℃/s
Cooling rate	Average cooling rate: From 90℃~50℃, it should not be less than 1.5℃/s Maximum cooling rate: From 90℃~50℃, it should not be less than 2.0℃/s
Accuracy of module temperature control	No more than 0.5℃
Temperature accuracy	The absolute value of the difference between the measured value and the set temperature should not be more than 0.5℃
Uniformity of module temperature	The temperature difference should be within ±1℃
Document format	csv
Operating system	android
Dimensions	283mm×192mm×120mm(L*W*H)
Weight	3.5kg

Appendix 2　Normative references

This manual is prepared referring to the following documents. For the dated documents, all subsequent amendments (excluding errata content) or revisions do not apply to this manual.

GB/T 25000.51-2010 Software Engineering Software Product Quality Requirements and Evaluation (SQuaRE) Requirements for Quality of Commercial Off-the-Shelf (COTS) Software Product and Instructions for Testing

Appendix 3   Glossary

Terminology	Description
CSV	The English abbreviation of Comma Separated Value is usually a plain text file. The file format used in the program to import and export data.
Ct (Cycle threshold)	In the real-time test and amplification process, the number of cycles is the Cycle threshold (Ct) when the fluorescence value reaches the threshold.

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