UltraFast QPCR Instrument

HC800

User Instruction Manual

CE IVD

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Instruction

Thank you for purchasing the UltraFast QPCR Instrument from Guangdong Hecin Scientific, Inc.
Before using, please read the Instruction Manual carefully. Please keep this Instruction Manual after reading for reference at any time required.

⚠ Caution

1. Don't use the Instrument in flammable and explosive substances places.
2. Don't wipe the Instrument by flammable substances (such as gasoline, paint,etc.). Otherwise a fire may be caused.
3. The Instrument only operates on 100-240VAC,50/60Hz, well-grounded power supply.
4. Don't use the Instrument for any purpose that may violate relevant laws and regulations.

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Preface

The Manual describes the use, function, and operation of the Instrument in detail. Please read this Manual carefully and use the Instrument correctly to protect patients and operation safe. Please place this Manual close to the Instrument so that it is available any time.

Application

The Instrument is operated by professional clinical medical staff or personnel with professional training.

Illustration

All illustrations provided in this Manual are for reference only, and the settings or data in the illustrations may not be exactly the same as those in the Instrument.

Table of Contents

Description on graphic symbols

S/N	Symbol Label	Location	Meaning
1		Carton	Users are advised to read the Manual before using.
2		Carton, Nameplate, Insturment	Caution! Consult the attached documents.
3		Instrument	Biological hazard
4		Carton	The transport package shall not be exposed to sunshine.
5		Carton	The transport package shall be kept upright during transportation.
6		Carton	The transport package contains fragile items, and shall be handled with care.
7		Carton	The transport package shall not be exposed to rain.
8	IVD	Nameplate	In vitro diagnostic medical devices
9		Carton	The maximum number of layers of the same transport packages to be stacked.
10		Power switch of Instrument	Switched off (main power supply)
11		Power switch of Instrument	Switched on (main power supply)
12		Ground pole	Protective grounding
13	~	Power interface of Instrument	AC
14	⎓	Nameplate	DC
15		Instrument sample well	Caution! Hot

Chapter 1 Safety Instructions

1.1 Cautions

- This Manual cannot represent the explanation for professional medical staff.
- Read this Manual before first using.
- The Instrument may be used in hospitals and other environments, but must be operated by professional medical staff or professional staff.
- This Instrument can only use the accessories and spare parts provided or specified by the manufacturer.
- The Instrument cannot be disassembled privately. Upgrading and maintenance must be carried out by the manufacturer.
- If there is an abnormal failure during use, please immediately stop using and contact the supllier or manufacturer.
- The protection provided by the Instrument may be damaged if the Instrument is not used according to the Manual.

1.2 Precautions

- The Instrument can only work normally at the ambient temperature required by this Manual. If it is used beyond the temperature, the performance of the Instrument will be affected or even be damaged, which may also injure the user.
- Before cleaning and maintenance, the power plug shall be removed;
- When the Instrumentis not used, turn off the power and remove the power plug.
- Avoid fire and heat sources and direct sunlight as far as possible during use.
- This Instrument cannot be used in environments where flammable gases, anesthetic gases, air/oxygen mixed with nitrous oxide exist.
- It does not cause electromagnetic interference to the surrounding environment, but strong electromagnetic interference may affect the performance and stability of the Instrument. Hence, the Instrument shall be placed away from electromagnetic interference sources.
- The Instrument shall be placed in a well-ventilated place, and shall not be placed on a soft surface such as a bed or sofa. Do not cover the Instrument with blankets or bedding, which may block the vents and cause overheat, This affects the Instrument.

- Fluff, hair, dust, liquid and other substances shall be prevented from entering the air inlet of the Instrument .
- Please place the Instrument in a well-ventilated place and keep a proper distance from the wall.
- Don't cover the surface of the Instrument with combustible materials (clothing, paper, etc.) to avoid a fire.

1.3 Contraindications

None.

Chapter 2 Product Introduction

2.1 Intended use

Based on the principle of fluorescence quantitative polymerase chain reaction, this Instrument is matched with detection reagents, which is clinically used for qualitative and quantitative detection of analytes in nucleic acid samples (DNA/RNA) derived from human bodies, including pathogens and human genetic items.

2.2 Test principle

UltraFast QPCR Instrument provides temperature environment for nucleic acid in vitro RNA reverse transcription and degeneration, annealing and cyclic amplification and melted setting parameters according to setting parameters, which is run by the communication module through the temperature control module. The Instrument uses the optical module to collect real-time fluorescence signal in amplification process, while data processing is done by application software. It is used for amplification and analysis of specific target genes or nucleic acid sequences in samples.

2.3 Specification

Product name: UltraFast QPCR Instrument
Model specification: HC800

2.4 Product structure

This Instrument is composed of control components, thermal cycle components, photoelectric components, transmission components, embedded software and analysis software(Version: V1.0), power supply components, etc.
The appearance structure of the Instrument is shown in Fig .2-1, 2-2, 2-3.

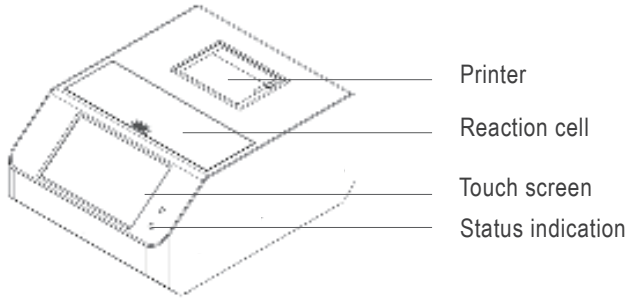


Fig 2-1

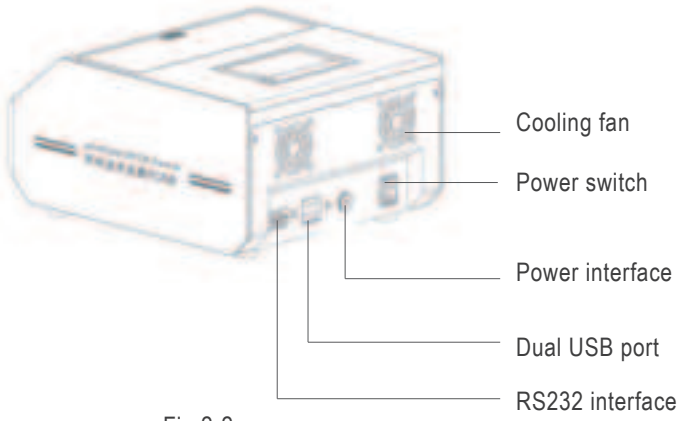


Fig 2-2

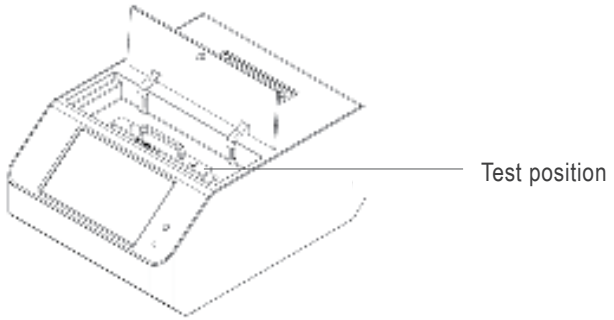


Fig 2-3

2.5 Software requirements

Software requirements	Software Name	UltraFast QPCR software	
	Model	HC001	
	Version	V1.0	
	Software operation environment	Minimum hardware configuration requirements	Cpu: 1.0 GHz;
			RAM: 1G;
			Display screen resolution: 852×480;
			GPU: 480 MHz.
		Operation Environment	Support android 5.0 and above
		Network access	None
Network security requirements	Data interface	The software carries out bidirectional data transmission through USB interface, and the transmission protocol is USB2.0	
		In debugging mode, the software uses storage media such as A USB flash drive or a portable hard disk to exchange electronic data in. CSV and. TXT formats.	
	User access control mechanism	The user password is used for permission access control, that is, the user password must be entered for permission access control before the import and export of experimental files.	
	Security Software	None	
	Requirements for software environment and security software updates	None	

2.6 Software basic functions

The software has the functions of search, experiment, project selection, process selection, fluorescence channel selection, result analysis, result export, print and help.

Chapter 3 Preparation

3.1 Unpacking and installation

Check if the overall packing is complete during unpacking. The packing attachment shall be consistent with the configuration list (Chapter 10). If the actual packing list is inconsistent with the configuration list (Chapter 10), please contact supplier or manufacturer.

Please keep the packing case and packing materials in case the Instrument needs to be repackaged in the future.

3.2 Woking environment

For the safety of users and the use of the Instrument, the operating environment must meet the following requirements.
(1) No direct sunlight, no strong electromagnetic radiation environment.
(2) Place in Ventilated and convenient operation environment;
(3) Do not use in the vicinity of strong light, flammable and explosive gas.
(4) The bearing weight of the installation table must be more than 50kg.
(5) The distance between the Instrument and the wall should be more than 10 cm to ensure good heat dissipation and ventilation of the equipment.
(6) Do not place the Instrument in a position where it is difficult to disconnect power.

3.3 Instrument installation

(1) Ensure that the instrument is turned off;
(2) Put the output end of the power adaptor into the Instrument power interface at the rear of the instrument;
(3) Connect the power cord plug of the adaptor to the power socket that meets the working requirements of the instrument.

Warning:
(1) Ac power must be well grounded;
(2) Please use the power adaptor and power cable supplied by the manufacturer;
(3) When inserting and unplugging the power cord, you should hold the plug instead of the power cord;
(4) If the Instrument appears smoke, odor or abnormal sound, immediately turn off the power and contact manufacturer;
(5) RS232 interface is only used for production debugging, working voltage DC5V, while the insulation value of external circuit should not be less than 1MΩ;
(6) USB interface connects to a storage tool such as a USB flash drive for data exchange, device upgrade, and maintenance.

3.4 Installation of reaction tube(8-tube PCR strip)

1. Fix reaction tube (direction: A to H) below the handle (direction: A to H) in the right direction. Please keep reation tube vertically.

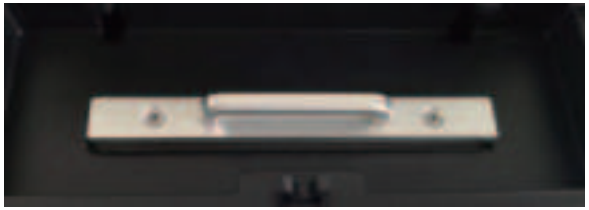
The reaction tube is fixed below the handle.

The specification of reaction tube shall be 0.1ml transparent thin-walled tube.

3.5 Placement of reaction cell

2. Place it in the reaction cell in a direction.

Place in the reaction cell



The reaction tube is placed in the reaction cell.

Note:

① Turn on the green light before test.

② After reaction solution is prepared, add 15-25μl paraffin oil on the surface of reaction solution.

③The specification of reaction tube shall be 0.1ml transparent thin-walled tube.

Chapter 4 Software

4.1 Startup

Turn on the instrument.

4.2 Self-check interface

After startup, the interface shows in Fig. 4-1A:

Fig. 4-1A

And it automatically jumps to the self-check interface in Fig. 4-1B.

Fig. 4-1B Self-check interface

After self-check interface, it enters the main interface. If no self-check shows, a red Ⓧ alert will pop up; if you need to re-test, please click the recheck button, if you need to skip the self-test interface, please click button "skip self-test" .

4.3 Main interface

As shown in Fig. 4-2, main Interface includes four items: Search, Exper., Set, Language and Help.

Search: Review previous test records by searching experiment date and No.

Exper.: Start a new test.

Set: Test-related item management. It also contains some less-common but special permissions settings.

Help: Instruction about the Instrument.

Language: Simplified Chinese or English for reference.

Fig. 4-2 Main interface

Common buttons in the left of the first line:

Back to the previous interface

More Settings

Back to main interface

Print

4.3.1 Test process

4.3.1.1 Normal mode Select Test Item

①Click button "Exper. " on main interface and jump to Fig. 4-3. Click button "Normal" and jump to Fig. 4-4A interface, which different tube positions can be set up.

Method: Select different tube positions, click button "Item" and enter the interface shown in Figure 4-5. If necessary, click button "Test Item" at the bottom right in Figure 4-5 for deletion and addition. Select qualitative or quantitative detection in Figure 4-6.

②Click button "Item" and return to Figure 4-4A interface.

③Click button “program” and jump to process selection interface in Fig. 4-7.

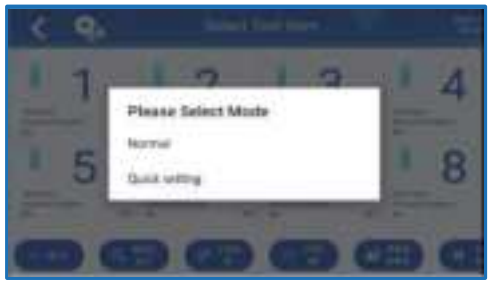


Fig. 4-3 Item selection interface

Fig. 4-4A Item selection interface

Fig. 4-5 Item selection interface

Fig. 4-6 Item Edit Interface

Program selection interface

Select program in Figure 4-7, click button "OK", jump to the sample type interface in Figure 4-4A. If necessary, click button "Program", click button "EDIT" and jump to Program Editing interface in Figure 4-8 for deletion and addition.

Fig. 4-7 Program selection interface

Fig. 4-8 Program Editing interface

Sample type interface

①Sample Type is shown in Fig. 4-4A, which is used to set the type and parameters of tube position.

Method: Click the tube position in Fig. 4-9, select sample type. The sample types include negative control, positive control, and samples to test.

②If sample type is a sample to tested. The sample number must be filled in.

③If quantitative analysis is selected in Figure 4-6, the sample type can be standard material, and fill in copies of standard material.

④After setting the sample, Click button "DONE" and jump the interface in Fig. 4-10 for checking the sample setting information and running program. At this time, click button "Back" for resetting (you can also rename the test and click button "Save" for the current test. And click "Load Profile" in quick setting), and click button "Run".

Fig. 4-9 Sample type setting interface

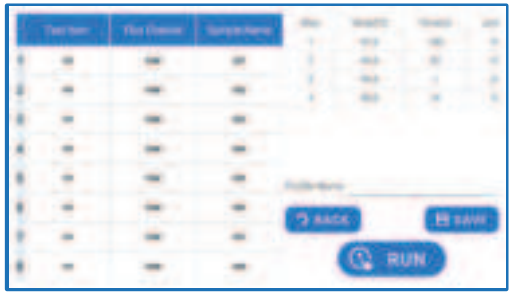


Fig. 4-10 Sample type setting interface

4.3.1.2 Quick setting interface

①Click button "Exper." on main interface, click button "Quick setting", jump to Fig.4-4B

②Click button “All”, click button "Load Profile", jump to profile interface in Fig.4-11 (in normal mode here).

③Click button "Load Profile", click “OK” and jump to Fig.4-10. Check the sample setting information and run the program. At this time, click button "Back to Edit" to reset, or click button "Run" button to start test.

Fig. 4-4B Item selection interface

Fig. 4-11 Load profile interface

4.3.1.3 Real-time display interface

①Real-time display interface is in Fig. 4-12 which the fluorescence curve of the selected channel and tube position are displayed dynamically in real time.

Method: There are four fluorescence channels CH1, CH2, CH3, CH4 and 8 tube positions include1-8 in the picture, which can be multiple selection. The curve area is dynamically updated according to the channel and tube position selection.

②Button "STOP" can stop the test in advance and analyze the existing data. Although the test is not completed, the operator believes that the result can be collected. The test can be terminated in advance. This operation is irrevocable, please be careful.

③The remaining detection time is calculated based on dynamic estimate of the test.

④After the test is completed, it will automatically jump to the result analysis interface in Fig. 4-13.

Fig. 4-12 Real-time display interface

4.3.1.4 Results analysis interface

①Result Analysis Interface displays the curve and result list in Fig. 4-13.

②There are CH1/CH2/CH3/CH4 recheck buttons in Fig. 4-13, which dynamically update the curve and result list according to the channel.
Second-order derivative algorithm is used to process data by default. In manual mode, the algorithm setting is selected as interpolation, and the threshold window is displayed under the curve area. Select a single channel, the threshold can be changed (The input box for multi-select channel thresholds is not available.). The curve and results will change accordingly based on the threshold.

③The results in the list can be changed. Select a row of results and the corresponding curve will be highlighted.

④ Click and view project information and rename the experiment (the experiment is named after the start by default). The name of the experiment should be different from that of the previous experiment, otherwise the result data will be lost.

⑤ Click to print the current experiment results.

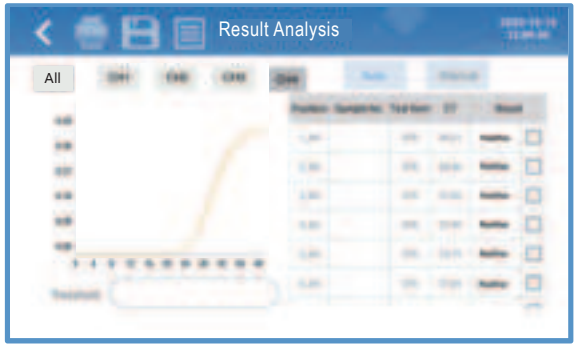


Fig. 4-13 Results analysis interface

Quantitative analysis

Figure 4-14 shows a curve and result list. The copy number of the sample to be tested is calculated by the copy number of the set standard, and CT value. Click the spline in the upper right corner to enter Figure 4-15, which displays the standard curve and related parameters. The linear regression equation is Y=KX+B, where K represents slope, B intercept, and R linear correlation coefficient.

Fig. 4-14 Record display interface

Fig. 4-15 Spline interface

4.3.2 Search

4．3．2．1 Result Search

Clich buttton Search in Fig. 4-2, then jump to interface as shown in Fig.4-16.

Search Interface is in Fig. 4-16. The Search interface has two searching method, by date and sample number. Input a date or number, jump to the search list. Click a specific item in the list and jump to the search result list.

Fig. 4-16 Search Interface

Select button "Date" , jump to the interface Fig. 4-17. Click the specific item in Fig. 4-17 and jump to Fig. 4-18.

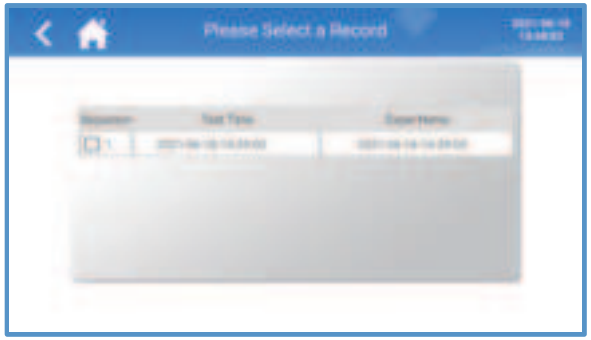


Fig 4-17 Select record Interface

Fig 4-18 Record display interface

4.3.2.2 Data export

Insert the USB flash drive to the USB Port.

Click button "Set" on the main interface (Fig 4-2), slide leftwards and jump to interface in Figure 4-19. Click button "OPER", jump to the password interface, enter the password to get to a new interface, then slide to the third interface as shown in Figure 4-20. Click button "DEBUG MODE", select button "Allow Export Date" in Figure 4-21. Return to the main interface in Figure 4-2, click button "Search" and jump to Figure 4-16, select the date, and jump to Figure 4-22. At this time, check the experimental data and click "EXPORT".

Fig 4-19 Stetting interface

Fig4-20 Oper mode interface

Fig 4-21 Debug mode interface

Fig 4-22 Record export interface

4.3.3 Setting

Set Interface is in Fig. 4-23:

Fig. 4-23 Set interface

4.3.3.1 Item management interface

Click button "TEST ITEM" in Fig. 4-23 and jump to Fig. 4-24. Click button "ADD" or "DELETE" for corresponding operations. After selecting an item, click button "EDIT" and jump to Item Editing Interface in Fig. 4-25.

Fig. 4-24 Test Item interface

Edit Interface sets up qualitative and quantitative parameters, various judgment parameters (i.e., negative control, positive control, sample negative and positive results).

Note:

Sub-item 1 corresponds to the fluorescence channel: FAM

Sub-item 2 corresponds to the fluorescence channel: VIC/HEX

Sub-item 3 corresponds to the fluorescence channel: ROX/Texas Red

Sub-item 4 corresponds to the fluorescence channel: CY5

Fig. 4-25 Item Editing Interface

4.3.3.2 Program setting interface

Click button "Prog Set" in the setting interface in Fig. 4-23 and jump to Fig. 4-26. Click button "ADD" or "DELETE" for the next operation. Select a process, click button "EDIT", jump to Process Editing Interface in Fig. 4-27.

Fig. 4-26 Prog set interface

Prog Editing Interface sets up the parameters of each step in the process, such as target temperature, duration, number of cycles and detect status.

Fig. 4-27 Prog editing interface

4.3.3.3 Algorithm setting interface

Left-slide and click button "ALGORITH" in Fig 4-19, jump to Fig. 4-28. The algorithm (second-order derivative algorithm, interpolation algorithm) for test data processing can be set. The interpolation algorithm sets whether the four channels (CH1/CH2/CH3/CH4) have automatically calculated thresholds or fixed thresholds.

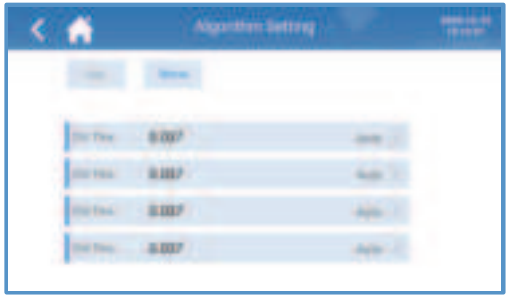


Fig. 4-28 Algorithm setting interface

4.3.3.4 Administrator mode interface

The administrator mode is only used in the manufacturer's after-sales maintenance, software upgrade and fault maintenance

All operations shall be carried out by the manufacturer.

4.3.4 Help

Click button "Help" in main interface in Fig. 4-3, jump to the interface in Fig. 4-29.

Fig. 4-29

Chapter 5 Technical Parameters

5.1 Performance parameters

Parameter	Value
Average heating-up rate	50℃—90℃，≥3.0℃/s
Maximum heating-up rate	50℃— 90℃，≥6.0℃/s
Average cooling rate	90℃—50℃，≥3.5℃/s
Maximum cooling rate	90℃— 50℃，≥ 6.5℃/s
Module control accuracy	≤0.5℃
Temperature accuracy	Absolute value of difference between measured value and set temperature ≤0.5℃
Temperature uniformity	±1℃
Temperature Accuracy in duration time	±5%
Repeatability	The CV of the Ct value shall not be greater than 3%.
linearity	r≥0.980
Fluorescent linear	Linear regression coefficient r≥0.990

5.2 Environmental parameters

Parameter	Working condition
Temperature	5℃～40℃
Relative humidity	20%~80%
Atmospheric pressure	85.0kPa-106.0kPa
Altitude	<2000m
Use location	Indoor

5.3 Electrical parameters

Parameter	Value
Dimensions	L*W*H，mm： 250×190×120
Weight	3.2kg（With power adaptor 3.8kg）
Input voltage	100-240VAC；
Frequency	50/60Hz；
Input power	90W
Overvoltage level	Ⅱ
Contamination level	2
Protection level of equipment shell	IPX0
Sample capacity	15-25 μl
Fluorescent dye	F1： FAM,SYBR Green Ⅰ;F2： HEX,VIC,JOE,TET,YELLOW;F3： ROX;F4： CY5
Chanels	4
Optical system	LED+MPPC

5.4 Rated parameters of dedicated adaptor

	Input	Output
Parameter	100-240VAC，50/60Hz, 1.3-0.6A.	15V ⎓ 6.0A，90W MAX
Grid voltage fluctuation range: 90-264VAC		

Chapter 6 Instrument cleaning and maintenance

6.1 Instrument cleaning

- Instrument surface cleaning: The instrument surface should be regularly wiped with soft cloth with a small amount of water and cleaned by a dry cloth.
  Reaction cell cleaning: If the reaction cell is contaminated with dust and
- impurities, it will affect PCR amplification and fluorescence detection. Therefore, it shall be cleaned regularly once every 3 months. It can be cleaned out with a blowing ball, or wiped with a small swab dipped in medical alcohol;
  Note: Turn off the power and unplug the power cord before cleaning.
- Note: Don't add any liquid into the reaction cell or in the Instrument directly. Don't
- clean the Instrument with corrosive or organic solvents.
  Note: If you have any questions about the compatibility of disinfectants or
- cleaning agents with the Instrument parts or materials, please contact manufacturer.

6.2 Instrument maintenance

- Do not switch on/off the Instrument frequently. Turn off the Instrument only after the self-check is completed.
- Do not turn off the power immediately after a test, keep the standby state for 5 minutes, and then turn off the power.
- Please use the power cord and adaptor provided by the manufacturer.
- Note: Non-professional maintenance personnel are not allowed to disassemble the device without authorization.

6.3 Indicator status

Indicator light	Status	Description
Red LED	On	The Instrument is power-connected normally.
	Off	The Instrument is not power-connected.
Green LED	On	The heating pool is working.
	Off	The test has not started, while the heating pool has not worked.

6.4 Common malfunctions and handling

No.	Malfunction		Cause	Handling
1	self-check	Communication module failed	Cable connection problem	Contact the manufacturer.
2		Motion module failed	Motor cannot be reset	Restart instrument.
3		Optical module failed	The scanning background fluorescence is too high	Check whether the reaction tube in the reaction pool is removed. The reaction tube should be removed after amplification and self-check should be performed again.
4		Temperature module failed	The ambient temperature is too low	The Instrument return to room temperature, and then conduct self-test again.
5	Program stop abnormally		Program running error or improper operation	Restart the instrument.
6	No results in the experiment		The experiment name is same with the previous experiment.	Retest and rename the test.
7			Reagents expired, invalid, or incorrect operation	Use another effective reagents and retest.
8			Setup error of program parameters	Set the experiment procedure according to the instruction.
9	Abnormal heating rate		Air vents and cooling holes are blocked	Clean the dust-proof nets.
10			Cable connection problem	Contact manufacturer.
11	The printer does not work		Insufficient paper	Manually add printing paper.

Chapter 7 Safety instruction

This Instrument has safety devices, so it can prevent accidents that may cause injury and damage to the user or the instrument. If improper use for the instrument, the safety devices may not work properly. Read carefully the instructions, cautions and precautions in this Manual before using.

- This Instrument is electromechanical equipment, which must be operated in strict accordance with the Instruction Manual.
- The Instrument can only be operated and maintained by trained laboratory personnel in accordance with the designated purpose and the Manual.
- The Instrument can only be repaired by the manufacturer.
- Before connecting power, make sure that the voltage and frequency of the AC power source are consistent with the requirements of the Instrument. When connecting power, make sure that the power switch is turned off.
- The Instrument must be connected to a three-core grounding socket that meets safety standards to prevent electric shock, with a rated voltage of 100-240VAC,50/60Hz.
- It is forbidden to shut down or unplug the power cord when the Instrument is running.
- It is forbidden to clean the Instrument when it is connecting power.
- Please turn off the power when the Instrument is no longer in use.
- This Instrument meets the emission and anti-interference requirements specified in this part of EN 61326-2-6.
- Keep away from strong electromagnetic interference environment to aviod affecting the operation or causing incorrect collection results. It is recommended to evaluate the electromagnetic environment in advance.
- Avoid direct exposure to strong light, because strong light will affect the operation of the optical module and cause incorrect collection results.
- Do not place the Instrument where it is difficult to operate the disconnect device (power plug/socket).
- External devices such as computers connected to this Instrument shall comply with the relevant national electrical safety standards or IEC electrical safety standards to avoid dangerous voltage or energy risks to this device.

- If the Instrument is not used for a long time, it is suggested to startup once every month regularly and check whether the self-check is operated.
- Use protective gloves and clothing when handling potentially infectious substances (such as human samples or reagents) that may come into contact with the skin.
- Do not turn on the Instrument to avoid burns during use.
- When using the Instrument for measurement or maintenance, the operator shall take good care to avoid possible biological contamination of samples or internal mechanisms, such as wearing gloves.
- In case of any damaged parts, please contact the manufacturer or agents in time. If hazardous substances leak to the Instrument, appropriate disinfection should be taken.
- Waste disposal should be handled according to relevant requirements (such as local regulations or reagent instructions).
- If the normal use involves the handling of dangerous substances, it must be operated by trained qualified personnel and take personal protective measures.

Chapter 8 Transportation and storage

8.1 Transportation

When the Instrument is delivered to user, the Instrument should be transported according to the labels on the packing box. The Instrument should be moisture-proof, rain-proof, and handled with care. The Instrument should not be mixed with inflammable and explosive items in transportation.

When the Instrument is not in use or transportation or disposal, it may be affected by residual biohazard sources in the Instrument. Biohazard sources on the Instrument should be effectively treated and controlled to minimize biohazards for operator safety. For example, wipe the surface of the Instrument with a neutral cleaning solution before stopping use.

8.2 Storage

The packaged PCR device shall be stored a well-ventilated environment at -20℃～55℃, with a relative humidity no higher than 85%, Atmospheric presure 85.0kPa-106.0kPa, but no corrosive gas.

8.3 Instrument transfer

After the instrument is installed and run normally, it should not be moved in case any damage of high-precision components and wearing parts inside the instrument, which will affect the normal operation of the instrument.
Please put the Instrument into the packing case if move. Handle with care.

Chapter 9 Disposal

For the disposal of the device or accessories, please contact the local authority and recycle it in accordance with relevant local laws and regulations.

Chapter 10 Configuration list

No.	Material name	Quantities	Specification
1	Ultrafast QPCR Instrument	1	HC800
2	Power Adaptor	1	GSM90A15-P1M
3	Wire assembly	1	3×0.75mm2
4	Instructions for use	1	/
5	Certificate of qualification	1	HM249-001
6	Warranty card	1	HM249-001

Chapter 11 Production date and service life

Service life of the Instrument: 5 years. This service life is determined according to the instrument life test. During the use, the user shall maintain the product in accordance with the requirements of the Manual. After maintenance, the Instrument can be used normally when basic safety and effectiveness are confirmed.

Appendix: Electromagnetic compatibility

⚠Caution：

- HC800 UltraFast QPCR Instrument meets the emission and disturbance resistance requirements specified in EN 61326-2-6. See Table 1 and Table 2 below.
- The user is responsible for the electromagnetic compatibility environment of the Instrument to work normally.
  It is recommended to evaluate the electromagnetic environment before using.

⚠Warning：

It is forbidden to use HC800 UltraFast QPCR Instrument in strong radiation environment(such as unshielded radio frequency sources). Otherwise the Instrument may be interfered.

Table 1:

Electromagnetic emission	
Emission test	Compliance
EN 55011 Conducted emission	Group 1 Class B
EN 55011 Radio frequency emission	
EN 61000-3-2 Harmonic emission	Class A
EN 61000-3-3 Voltage fluctuation/flicker emission	Applicable

Table 2：

Electromagnetic immunity			
Immunity test item	Basic standard	Test value	Compliance criteria
Electrostatic discharge（ESD）	EN 61000-4-2	Contact discharge:±2kV、±4kV Air discharge:±2kV、±4kV、±8kV	B
Radio frequency electromagnetic field	EN 61000-4-3	3V/m，80MHz～2.0GHz，80%AM	A
Pulse burst	EN 61000-4-4	Power cable：±1kV(5/50ns,5kHz)	B
Surge	EN 61000-4-5	Wire to ground：±2kV Wire to wire：±1kV	B
RF conduction	EN 61000-4-6	Power cable：3V/m，150kHz～80MHz，80%AM	A
Power frequency magnetic field	EN 61000-4-8	3A/m，50/60Hz	A
Voltage dips, interruptions	EN 61000-4-11	0% at 1 cycle; 40% at 5/6 cycle; 70% at 25/30 cycle; 5% at 250/300 cycle	B C C C

Performance judgment:
A. During the test, the performance is normal within the specification limits.
B. During the test, the function or performance is temporarily reduced or lost, but it can recover by itself.
C. During the test, the function or performance is temporarily reduced or lost, but operator intervention or system reset is required.