Operation Manual

Version 1.2

Gene-8C Isothermal Fluorescence PCR





Hangzhou Allsheng Instruments Co.,ltd.



Foreword

Thank you for purchasing our Isothermal Fluorescence PCR. This Manual describes the function and operation of the instrument. In order to use the instrument properly, please read this manual carefully before using the Instrument. Keep it for later use when you meet with difficulties.

Opening check

Please check the instrument and accessories with the packing list when you first open the packing case. If you find any wrong or missing, please contact the distributor or the manufacturer.

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Safety warning and guidelines

1. Important information for safety using

Please have a comprehensive understanding of how to use before the operation. Therefore, read this manual carefully before using it.



Any improper operation before reading the manual is forbidden, otherwise instrument may cause injured or electric shock. Please read below safety tips and guidelines, and take precautions to ensure safety.

2. Security

The operation, maintenance and repair of the instrument should comply with the basic guidelines and the remarked warning below. Otherwise, the instrument might lose the warranty qualification and short the using life.



The instrument conform to class I of GB 4793.1 standard. Suggest use this instrument indoors or outdoors place where avoid light.



Please read this manual carefully before operate the instrument. Only the person who have the skill or experience of using this instrument is able to operate it.



Disassemble the instruments without permission is forbidden. This will make you lose the warranty qualification or have the risk of electric shock.



Make sure the voltage of the power supply is consistent with the required voltage of the instrument before connecting the power supply. And make sure the rated load of the power outlet is not less than required by the instrument.

If the power cord is broken, please replace it with the same type and specification power cord. Do not cover anything on the instruments when using. And do not put the power cable in the place where personnel ambulates.

Insert and pull the power line with hand gently and make sure the plug completely insert to the jack.



The heating block is hot and may cause the scald when the instrument is working, please make sure the temperature is cool when you touching it.

The instrument should be kept in a place with low humidity and dust. Away from water, direct sunlight and strong light source. The room should be well ventilated, free of corrosive gases or strong magnetic field interference, away from the heating furnace and other heating sources.



The air vents on this instrument are designed for ventilation.

To avoid overheating, do not block or cover it. When many instruments are used at the same time, the distance between each instrument should be more than 30cm.



Placed the instrument on the horizontal and stable platform where away from water and dust during the outdoors using. The instrument should be kept in a cool, clean place and avoid directly sunlight, strong light to make sure Fluorescence detection can be used normally.



When using lithium battery, make sure the ambient temperature is not too high, ambient humidity within allowable range, and in the place where with less dust and away from water sources (eg: pool, water pipe).



Power off when you finish the work. Pull off the connector plug when there's long time no use of the Instrument and cover it with a soft cloth or plastic paper to prevent from dust.

Pull the connector plug from the jack at once in the following cases, and contact the distributor or manufacturer:

- There is some liquid flowing into the Instrument;
- Drenched or fire burned.
 - Abnormal operation: such as abnormal sound or smell.
 - Instrument dropping or outer shell damaged.
 - The function has obviously changed.



Clean the inspection hole and disinfect the instrument with ultraviolet light before transport please.

Retain the original package for transport using to avoid damage during transportation.

3. Warning label



Warning: Hot surface, risk of scald.

4. Maintenance

1) Instrument cleaning

Surface cleaning

- a. The surface of the instrument should be cleaned regularly with a soft cloth with a little water.
- b. If any reagent is flowing into the surface of the instrument, wipe it with soft cloth with 70% alcohol.

Reaction hole cleaning

- a. If the reaction hole is contaminated by dust or impurities, amplification and fluorescence detection will be affected. So If there is any foreign matter to clean, users should wipe it slowly by the balloons.
- b. Turn off the heating lid to prevent the reaction hole from the dust when not use.
- c. Wipe the sample hole with clean soft cloth with 70% alcohol if reagent entered.



Before cleaning the instrument, turn off the power and remove the power cord please.



Do not dump the liquid in the reaction module or inside the instrument.

2) Instrument protection

- a. Do not power on and off the instrument frequently.
- b. Power off the instrument after the block temperature cooling to ambient temperature, as well as the fun will keep working about 10 minutes after the experiment finished.
- c. Please use the power cord and communication wire provided by the manufacturer.
- d. Please do not disassemble the instrument without the authorization.

3) Waste treatment

- a. After each experiment, there's a lot of amplification in the tube. To avoid contaminating laboratory and instruments, it should be dealt with according to regulations as soon as possible.
- b. Do not open the tube when removing it from the reaction module, otherwise the laboratory will be contaminated by high concentrations nucleic acid .

4) Over temperature protection

- a. The heating system of the instrument is provided with an overheat protection device. This device will be disconnected automatically and unrecoverable. And the heating system cannot continue to heat or cool.
- b. Please stop using and contact with the distributor after the heating system failed.

5. Requirement for transportation and storage environment

Ambient temperature range: 10 °C ~40 °C

Relative humidity range: ≤70%

Atmospheric pressure range: 750~1060hpa

Non-corrosive gas and well-ventilated environment

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Chapter 1 Introduction

Gene-8C Isothermal Fluorescence PCR is used for isothermal amplification and fluorescence real-time detection of samples. It is widely used in rapid detection of pathogenic microorganisms(viruses, bacteria, fungi, mycoplasma, parasites etc.), clinical disease diagnosis, food hygiene inspection, environmental monitoring, sex identification of animal embryos and detection of genetically modified food. It equipped with humanization operating system which help users read the results directly.

Characteristics:

- ❖ Long life LED cold light source fluorescence excitation and high stability photoelectric detection.
- ❖ With the function of anneal curve heating rate setting, the experiment is more accurate.
- Real-time amplification curve monitoring, the thresholds can be set manual or automatically.
- Support WIFI data transfer mode.
- Connect thermal printer by USB port.
- Small on stage, easy to carry.
- With built-in rechargeable lithium battery, durable and weather proof, it can be used in the field.
- Peltier component from Marlow brand.
- Open-ended thermostatic fluorescence detection reagent.
- ❖ Large operation screen operation with mobile phone APP and PC software.

Chapter 2 Features

1. Normal Operating Conditions

Ambient temperature range: 10 $^{\circ}\text{C}$ ~35 $^{\circ}\text{C}$

Relative humidity range: 20%~75%

Power supply: Input AC 100~240V, 50Hz~60Hz

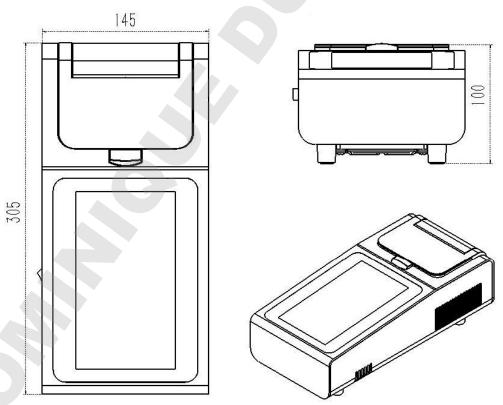
Output DC15V, 8A

2. Basic Parameters and Performance

Z. Basic Parameters and Performance						
	Product model	Gene-8C				
Technical paran	neters	Gelle-8C				
	Capacity	0.2mL - 8wells				
		(Strip of 8 tubes)				
Sample plate		10-150μL				
	Reaction system	(Recommended 20-30μL)				
	Applicable dye	FAM/SYBR Green I etc.				
	Temperature range($^{\circ}\!\mathbb{C}$)	15℃~99℃				
	Maximum heating rate(${}^{\circ}\!\mathbb{C}$)	2℃/s				
T	Maximum cooling rate(${}^{\circ}\!\mathbb{C}$)	2°C/s				
Temperature	Temperature uniformity(${}^{\circ}\!\mathbb{C}$)	±0.15℃@39℃				
control	Temperature accuracy/					
	Control accuracy(°C)	±0.2℃ / 0.1℃				
	Heating lid function	Yes, temperature is adjustable				
	Channel	Single				
	Excitation wavelength	470nm				
Ontical source	Detection wavelength	535nm				
Optical source	Excitation light source/ Detection method	LED cold light source/				
		Real-time fluorescence signal				
		detection				
		Analyzing and determining the				
Function	Data Analysis	positive or negative directly				
		according to the samples				

	Result display mode	1. positive /negative
		2. peak time 3. Tm value
	Determining method	1. Construct the amplification
		curve 2. Automatic
		instrument determination
	Display	7-inch touch screen
	Control software	Instrument and PC software,
		Android mobile app software
	Input power	100~240V,50~60Hz
Power supply	Lithium battery	Rechargeable battery
		(optional)
Dimensions&	Dimensions(W*D*H)	145*305*100mm
Weight	Weight	2.3kg

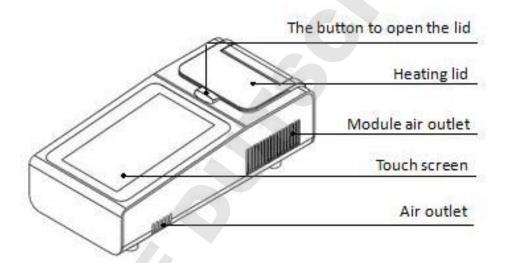
3. Drawing of Overall Dimensions



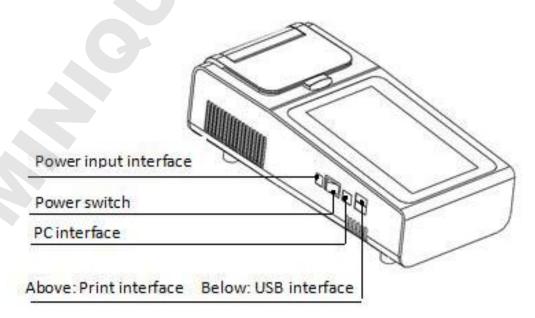
Chapter 3 Basic Operating Instructions

This chapter mainly introduces the structure of the instrument, operation keys and display content, as well as the preparatory work before starting up. Please have a comprehensive understanding about the instrument before the first time using.

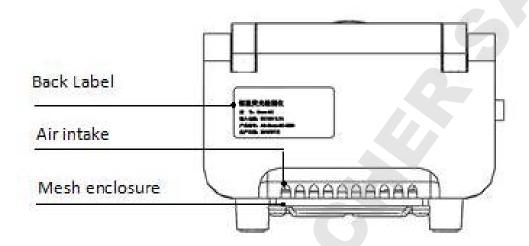
Structure 1.1. Front



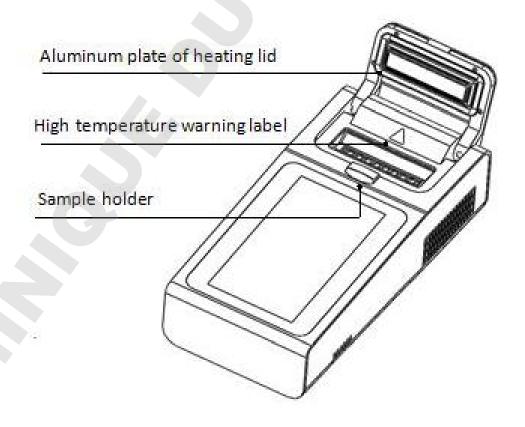
1.2. Side



1.3. Back



1.4. Reagent Test Area(Open the lid)



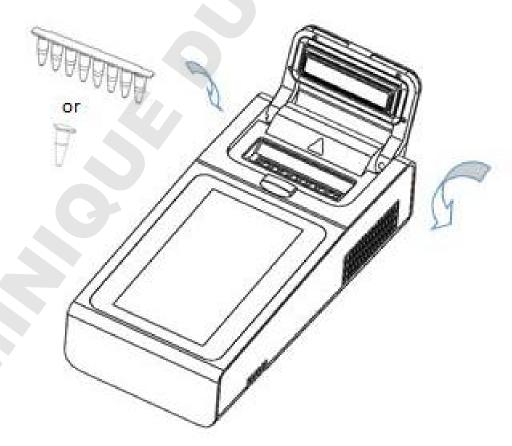
Chapter 4 Operation Guide

1. Power Connection

Take out the power adapter from the carton, then connect the power adapter with the power input interface on the side of the instrument. The other end of the adapter should connect the AC 220V power socket (it can work normally between AC100 $^{\sim}$ 240V). Power on switch on the side of the instrument to begin the operation.

2. Kit Installation

- Press the open lid button—The heating lid will open automatically.
- Put the reagent tube with the sample in the sample holder, ensure it at the correct place.
- Close the heating lid gently, it will be closed well when listening "click" sounds.



The instrument can use Flat top 0.2ml single tube or Strip of 8 tubes, but it is forbidden to mix them in one operation.

3. Instrument Operation

3.1. Startup Interface

The screen displays the startup interface after switch on the instrument. The version number and progress point are flashing in the startup process. As shown in Figure 4.1.



Figure 4.1 Startup Interface

After the completion of startup, it enters the detection Interface.

3.2. Test Interface

The test interface includes three mode of templates: isothermal amplification, isothermal anneal and anneal detection. As shown in Figure 4.2, it can be used to create and run experiments quickly, but users can not set parameters in these templates.

<u>Different experimental types of templates should be set up in different steps as below:</u>

Amp.: preheating, isothermal

Amp.&Anneal: preheating, isothermal, anneal

Anneal: anneal

Test Interface, Data Interface, Settings Interface can be switched to each other.

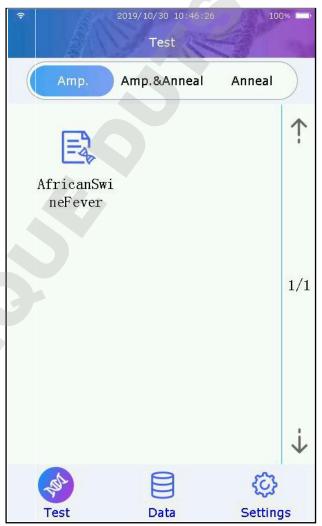


Figure 4.2 Test Interface

3.3. Fast start experiment

Under the test interface, select the template you need. Input the name and click "ok" on the pop up dialog to enter the running interface. Click "cancel" to close the dialog box. As shown in Figure 4.3.

The prerequisite for a fast start experiment is the existence of an end-of-run program.



Figure 4.3 New Experiment Setting

After creating the experiment, it will automatically switch to the results interface. As shown in Figure 4.4, this interface is not running now without any data. Click icon to back to the previous interface.

Run: Click the button and begin the operation.

CH 1/2: Display according to the channel setting, channel 1 is opening now, channel 2 is closed.

Export: Forbidden(No running,no data)

Print: Forbidden (No running,no data)

Program Interface, Temperature Interface, Amplification Interface, Anneal Interface, Results Interface can be switched to each other.



Figure 4.4 Results Interface

Switch to the program interface, as shown in Figure 4.5.

The parameter is only for review but can not be changed on this interface.

Preheat: Display preheating Temp. and Time.

Isothermal: Display isothermal Temp., Time and Measure period.

Anneal: Display Temp.1, Time, Temp.2, Ramp rate and Measure period.

Channel: Display Channel 1, Channel 2 Open and Close.

PN Factor, Tt Factor, PN limit is the determination condition of amplification peak.

And, Judge positive, weakly positive and negative by the set peak time.

The current real-time temperature, progress bar, remaining time and total experimental time are displayed at the bottom of the interface.



Figure 4.5 Program Interface

Switch to the temperature interface, as shown in Figure 4.6, it is used to display temperature curves. There is no data displaying now because there is no experiment running. The x-coordinate is time and the y-coordinate is temperature.

- +3 Minute: Preview status, unavailable/experiment running status, available:
- +5 Minute: Preview status, unavailable/experiment running status, available;
- +10 Minute:Preview status, unavailable/experiment running status, available:

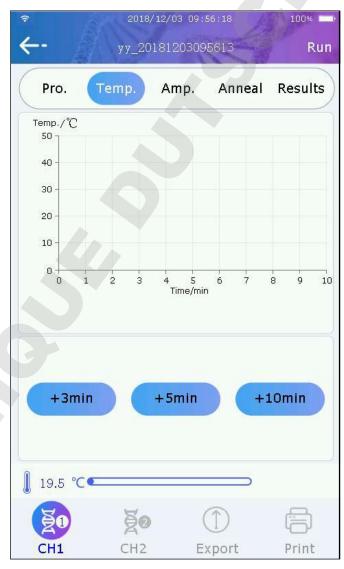


Figure 4.6 Temperature Curves Interface

Switch to the amplification interface, as shown in Figure 4.7, it is used to display amplification curves. It will display different colored curves according to different channel color. Users can choose to show or hide curves by clicking the color. The x-coordinate is time and the y-coordinate is fluorescence intensity.

Normalization: after clicking, all holes were placed in the same fluorescence intensity during the baseline period. The following figure has no data and no effect when clicked.

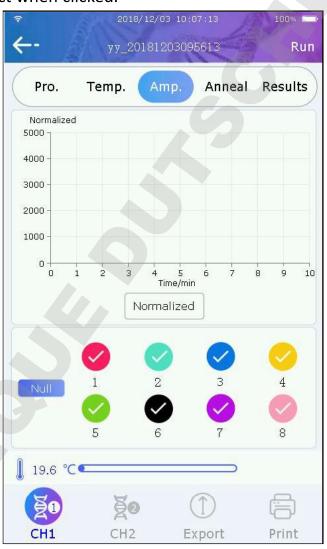


Figure 4.7 Amplification Curves Interface

Switch to the anneal interface, as shown in Figure 4.8, it is used to display anneal curves. It will display different colored curves according to different channel color. Users can choose to show or hide curves by clicking the color. The x-coordinate is time and the y-coordinate is fluorescence intensity.

Fluorescence curve: real-time detection data that can display fluorescence value.

Derivative curve: shows the differential corresponding to the fluorescence curve.

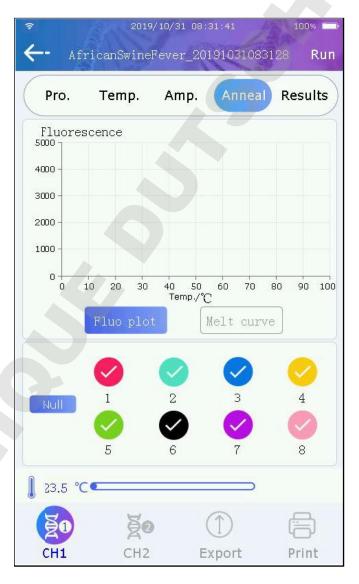


Figure 4.8 anneal Curves Interface

3.4. Data Interface

Click the data icon to switch to data interface. As shown in Figure 4.9, the data interface separates daily programs by date to check data and manage data. E.g.:The figure shows Isothermal amplification of 3 groups of experimental data on July 12, 2018.

Amp Interface, Amp.&Anneal Interface, Anneal Interface can be switched to each other. It will return to above 3 interfaces when switch the file.

Eack to the previous interface.

manage: Manage the current experimental data by click the button.

data: it will display experimental name, experimental date, users can click the button to view the data.

Pages up and down: users can click the ______ to page up and down.

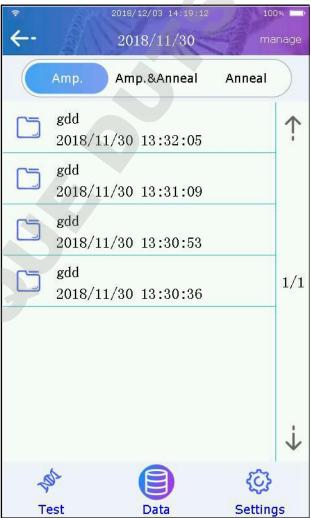


Figure 4.9 Data Interface

3.5. Experimental Data

Click result to review the data on result interface. As shown in Figure 4.10, The info of well position, sample name, results, Amp. and Peak Value etc will be shown. The info of Amp. and Peak Value will be shown when the result is positive.

Export: export data to USB flash disk.

Print: connect the printer to print the result data.



Figure 4.10 Result Interface

Switch to the program interface, as shown in Figure 4.11, it will display the parameter setting of the running program.

Preheat: Display preheating Temp. and Time.

Isothermal: Display isothermal Temp., Time and Measure period.

Anneal: Display Temp.1, Time, Temp.2, Ramp rate and Measure period.

Channel: Display Channel 1, Channel 2 Open or Close.

PN Factor, Tt Factor and PN limit. Data can be changed at this interface. After the change, experimental results will be recalculated according to the latest judgment conditions, and the results will be changed synchronously on the result interface

The same to Positive, weakly positive and negative.



Figure 4.11 Program Interface

Switch to the temperature interface, as shown in Figure 4.12, it will display

the temperature curves if there is experimental data.

The x-coordinate is time and the y-coordinate is temperature.

- +3 Minute: Preview status, unavailable/experiment running status, available:
- +5 Minute: Preview status, unavailable/experiment running status, available:
- +10 Minute:Preview status, unavailable/experiment running status, available;

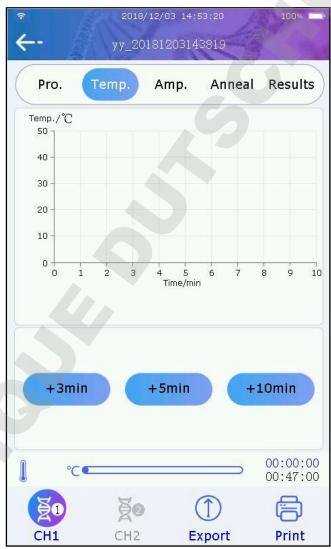


Figure 4.12 Temperature Curves Interface

Switch to the amplification interface, as shown in Figure 4.13, it is used to display amplification curves if there is data. The different colored curves displaying according to different channel color. Choose to show or hide

curves by clicking the color. The x-coordinate is time and the y-coordinate is fluorescence intensity.

Normalization: after clicking, all holes were placed in the same fluorescence intensity during the baseline period. The following figure has no data and no effect when clicked.



Figure 4.13 Amplification Curves Interface

Switch to the anneal interface, as shown in Figure 4.14, it is used to display anneal curves if there is data. The different colored curves displaying according to different channel color. Choose to show or hide curves by

clicking the color. The x-coordinate is time and the y-coordinate is fluorescence intensity.

Fluorescence curve: real-time detection data that can display fluorescence value.

Derivative curve: shows the differential corresponding to the fluorescence curve.

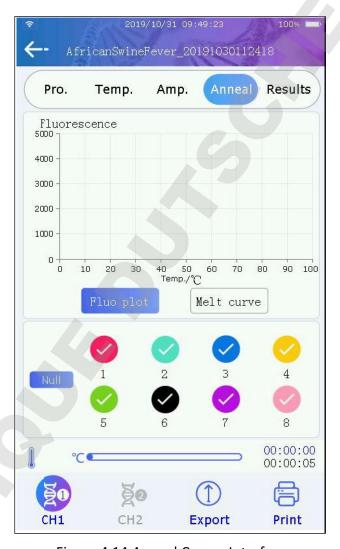


Figure 4.14 Anneal Curves Interface

3.6. Data Management

Click "Management" to manage the data.

As shown in Figure 4.15, users can delate and send files(in development) in this interface. Click "close" to exit from the management interface.



Figure 4.15 Data Management Interface

3.7. Setting Interface

Setting Interface included Experiment, Sample Name, Color, Language, System, Data Transfer, Information. As shown in Figure 4.16



Figure 4.16 Setting Interface

3.8. Experiment Setting

Click the Experiment Setting to switch to the interface as shown in Figure 4.17

New: Click it to create a new experiment on the pop-up dialog box.

In the Isothermal amplification interface, it will build a new Isothermal amplification template.

Edit: Choose the template and click the edit, it will enter Edit interface.

Rename: Choose the template and click the icon, users can rename the template in the pop-up dialog box.

Save as: Choose the template and click the icon, users can input the name in the pop-up dialog box.It will be saved as a new template and the original template is retained.

Manage: Click and enter the management interface to manage current experimental templates.



Figure 4.17 Experiment Setting Interface

The operation is same between "new" and "edit" interface (Parameter setting is different). As shown in Figure 4.18, it is the setting for Isothermal Anneal experiment. <u>Different experimental mode of templates can be set up in different steps as below.</u>

Isothermal amplification: Preheat, Isothermal

<u>Isothermal anneal: Preheating, Isothermal, Anneal.</u>

Anneal test: Anneal.

Preheat: open and close (below figure is opening); set the preheating temperature; set the preheating time.

Isothermal: set isothermal temperature; set isothermal time; set isothermal period.

Anneal: set temperature 1; set anneal time; set temperature 2; set rate; set measure period.

Default peak judgment: the instrument defaults to positive, weak positive and negative judgment. By default, the peak before 2/3 of the total time of the experiment was positive, and the peak before the experiment was negative, while the peak before the experiment was weakly positive.

Click the little blue button to change the decision time or remove the weak positive option.

Advanced: Click the button to enter Advanced Setting Interface.



Figure 4.18 Isothermal Anneal Experiment Setting Interface

As shown in Figure 4.19, In the advanced setting, channel, peak determination conditions (PN coefficient, Tt coefficient, PN limit) and sample name in the hole location can be set.

"PN Factor", "Tt Factor" and "PN limit" provide the basis for the determination of negative, positive and weakly positive. When creating a template, you can select the default Settings of the instrument, or adjust the peak judgment parameters according to the type of the experimental reagent.

Parameter	Paraphrase	Can set range	
PN Factor	"Positive&Negative coefficient" is one of	0.001 ² 0.0FF Th	
	the two necessary conditions to	0.001~0.255, The default is 0.02	
	determine positive/weak positive.		
Tt Factor	"Time threshold coefficient", the Time	0.001~0.255, The	
	value of positive/weak positive judgment	default is 0.02	
	results.	And Tt Factor ≤PN	
	resuits.	Factor	
PN limit	"Positive&Negative limit" refers to the		
	difference between the fluorescence		
	intensity at baseline and the fluorescence	200~30000, The	
	intensity at plateau, and the difference	default is 10000	
value ≥PN limit is one of the necessary			
	conditions for the determination of		
	positive/weakly positive		

Table 1 definition of three parameters



Figure 4.19 Channel Setting Interface

Manage the Isothermal amplification template in the management interface. As shown in Figure 4.20.

Delete: delete the chosen template. Export: export the chosen template.

Send: in development



Figure 4.20 Experimental Template Setting Interface

3.9. Sample Name Library

Edit and delete the chosen template under sample name interface. (Default selection is the first sample name) As shown in Figure 4.21.



Figure 4.21 Sample Name Library Interface

3.10. Color Management

Enter to color management interface, default selection is the first color. As shown in Figure 4.22. Select the sample graph and choose the color for it.

Save: save current setting

return the previous interface. It will remind users if not save.

Default: Click to restore the default Settings

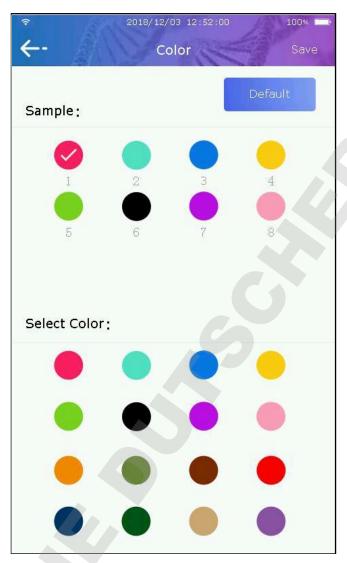


Figure 4.22 Color Management Interface

3.11. Language Setting

Choose Chinese or English in Language setting interface. As shown in Figure 4.23. click to switch it after selection.



Figure 4.23 Language Setting Interface

3.12. System Setting

System setting include Battery, Wifi (in development), Time, Screen, Update, Maintain. As shown in Figure 4.24



Figure 4.24 System Setting Interface

3.13.1. Battery Management

Battery management include screen darkening time, screen darkening level, stand-by time, Peltier cooling. As shown in Figure 4.25.

Screen dim time: set screen darkening time(min)
Screen dim level: set screen darkening level(%)

Standby time: set stand-by time(min)

Peltier Enable: set on or off

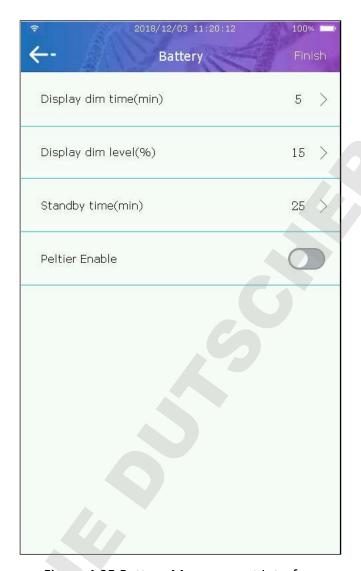


Figure 4.25 Battery Management Interface

3.13.2. Time Setting

Set time and date in time setting interface. As shown in Figure 4.26

Time: set the time in the pop-up dialog box after clicking.(hour: minute: second)

Date: set the date in the pop-up dialog box after clicking.(year: month: day)



Figure 4.26 Time Setting Interface

3.13.3. Screen Setting

Adjust the screen brightness by slide left or right towards. As shown in Figure 4.27.



Figure 4.28 Screen Setting Interface

3.13.4. Software upgrade

Click upgrade to upgrade the software after insert the usb flash disk. "Insert the usb flash disk" dialog will be popped up if there is no usb flash disk

3.13. Data Transfer

The printer could be set as print automatically here. As shown in Figure 4.29 Auto Send function is in development.



Figure 4.29 Data Transfer Interface

3.14. Instrument information

Version number and SN number is display in this interface. As shown in Figure 4.30



Figure 4.30 Instrument information Interface

Chapter 5 Troubleshooting

Fault analysis and solutions

No	Fault phenomenon	Reason analysis	Solutions	
1		No power supply	Check power supply	
	No display after switch on	Adapter not plugged in well	Check plug and reinsert	
		Switch failure	Replace switch	
		Others	Contact with distributor	
2	Flach carean	The power is not connected properly	Check the power supply	
	Flash screen	Touch screen signal line failure	Contact with distributor	
3	Incorrect temperature value	Sensor failure	Contact with distributor	
4	Radiator/block/hea ting lid temperature alarm	Thermistor failure	Contact with distributor	
5	The cooling fan	Stuck by paper scrap,foreign body	Clean up or contact with distributor	
	doesn't work	Burn down	Contact with distributor	
6	Abnormal sounds of cooling fan	Stuck by paper scrap,foreign body	Clean up or contact with distributor	
		Fan failure	Contact with distributor	
_	Block can not	Peltier failure	Contact with distributor	
7	heating or cooling	Control unit failure		
	The LED light does	LED light failure	Contact with distributor	
8		Connection line failure		

	Abnormal fluctuation of	There are foreign bodies in the well	Contact with distributor
9	baseline	Detection board /	
	fluorescence	silicon photocell	Contact with distributor
	curves	failure	
		There are foreign	Clean up or contact with
	Baseline	bodies in the well	distributor
10	fluorescence	LED light failure	Clean up or contact with
	value is abnormal	LED light failure	distributor
		Optical fiber failure	Contact with distributor

Software fault alarm table

Fault type	Name	Alarm content
RAM	Memory chip read failed.	Memory read failed.
Touch screen	Touch chip read failed.	Touch chip read failed.
Acquisition board	Capture chip read failed.	Capture chip read failed.
	Module temperature	Module temperature sensor
Module	sensor open	error.
temperature	Module temperature	Module temperature sensor
	sensor short	error.
Heating lid	Lid temperature sensor open	Lid temperature sensor error.
temperature	Lid temperature sensor short	Lid temperature sensor error.
	Radiator temperature	Radiator temperature sensor
Radiator	sensor open	error.
temperature	Radiator temperature	Radiator temperature sensor
	sensor short	error.

Chapter 6 Accessories

No	Name	Specs	Unit	QTY	Remarks
1	Power cord		Рс	1	According to the order
2	Power adapter	EDAC	Pc	1	
3	Operation Manual		Рс	1	
4	QC Certificate		PC	1	
5	Battery charger	4 position	Pc	1	Optional
6	lithium battery	26650	Pc	4	Optional

Chapter 7 Abbreviations and Tags

Abbreviations

The following Abbreviations are for reference and will appear in this operation manual.

А	Ampere	
AC	C Alternating current	
V	Volt	
Hz	Hertz	
W	Watt	
USB	Universal Serial BUS	
WiFi	Wireless Fidelity	
Kg	Kilogram	
mm	Millimeter	
μL	microliter	
$^{\circ}\mathbb{C}$	Degree centigrade	
CV	stability	
RUN	Run	
STOP Stop		

Warning markings used on the instrument



