Galaxy Pro

Automated Fully Enclosed qPCR Instrument

Galaxy Pro User Manual

Igenesis

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Automated Fully Enclosed qPCR Instrument Galaxy Pro User Manual

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Name of Manufacturer：Igenesis (Shanghai) Co., Ltd.

Manufacturer Address：Floor 3, Building 1, Lane 500, Furonghua

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Preface

Description

Thank you for purchasing Galaxy Pro Automated Fully Enclosed qPCR Instrument (hereinafter referred to as "Galaxy Pro").

Please read this manual carefully before using the instrument so as to use the product properly. Please keep this manual with care after reading so that it can be consulted at any time when necessary.

Product Name: Automated Fully Enclosed qPCR Instrument

Product Model: Galaxy Pro

Intended Use: Galaxy Pro Automated Fully Enclosed qPCR Instrument can be used for real-time fluorescence PCR experiment and analysis. The instrument can be operated in a laboratory or in a stable environment and together with corresponding detection reagents. It can automatically complete the extraction and purification of nucleic acid, QPCR amplification and result analysis.

The Relevant Labels of Galaxy Pro

Symbol	Description
	Protective Grounding: Identifies the terminal connected to the outer protection conductor to prevent electric shock in case of failure.
	Alternating Current: Identify the terminals for AC power, indicating that the equipment is only suitable for AC power.
	Manufacturer
	Date of Manufacture
	Refer to instructions for use.
S N	**Serial Number**
IVD	**In Vitro Diagnostic Apparatus**

	Temperature Limit
	Expiry Date
	Fragile, handle with care: Indicates that the product or some of its components are fragile and reminds handling personnel to handle it with care.
	Avoid Rain: Indicates that the product is afraid of rain and should be kept dry.
	Upper: Indicates that this arrow is kept upward during transportation of this product.
	No Hand Hook: Indicates that hand hooks are not allowed when handling transport packages.
	No Stacking: Indicates that the package is only allowed to be stacked in a single layer.
REF	**Reference**: Catalog number.
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC

Contact Information

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Intellectual property

Copyright of ©2015—2023Igenesis (Shanghai) Co., Ltd. (hereinafter referred to as "Igenesis"). All rights reserved.

The intellectual property rights of this product and its user manual belongs to Igenesis. No person or organization shall copy, distribute, excerpt, modify or translate any part of this user manual without the written consent of Igenesis.

Statement

Igenesis owns the final right to interpret this user manual.

Only when all of the following requirements are met, Igenesis will take the responsibility upon safety, reliability and performance of the product:

- The product Installation, debugging, maintenance, repair and improvement shall be conducted by professionals from Igenesis.
- All spare parts and consumables for maintenance are original (factory-packed) Igenesis from or approved by Igenesis.

- The application environment of this product shall be in conformity with the requirements of this user manual.

- The operation of the instrument shall be carried out according to this user manual.

- **Instrument Service Life**: 8 years. The service life is confirmed by the aging test. Please use, clean and maintain the instrument according to the user manual.

- **Instrument Maintain Period**: Every 12 months. Please contact the after-sale service.

- **Instrument Calibration Period**: Every 12 months. Please contact the after-sale service or the qualified agency.

Warranty and Maintenance

- The warranty period of the product is 15 months.

- The consumable mentioned in this user manual is the disposable consumable or vulnerable material that needs to be replaced after each use, and the consumables have no warranty.

- The warranty period starts from the "Delivery date".In order to safeguard your rights and interests, please fill in the warranty card correctly after the installation of the equipment, and give the second copy of the warranty card (retained by Igenesis) to the installation personnel or post it back to the user service department of Igenesis.

- Please note that the following conditions will not be covered by the warranty:

- The equipment serial number provided by the user is incorrect (Igenesis confirms whether the warranty is guaranteed by the equipment serial number.).

- Disassemble the instrument without the approval of Igenesis.

During the warranty period, all products enjoys free after-sales service. However, please note that even if the products need to be repaired during the warranty period, Igenesis will implement the chargeable maintenance service due to the following reasons, and user needs to pay for the maintenance fee and accessories fee:

- The product is not operated according to the user manual.

- Artificial damage.

- Improper use

- User does not follow the user manual to operate the instrument.

- The grid voltage exceeds the specified range of the product.

- Unexpected natural disasters.

- Replace or use parts, accessories and consumables that are not approved by Igenesis, or repair them by personnel not authorized by Igenesis.

- Other faults not caused by the product itself.

- After the expiration of the warranty period, Igenesis can continue to provide chargeable maintenance service. If your party do not pay or delay to pay the chargeable maintenance service fee, Igenesis will suspend the service until you pay.

After-sale Service

- **After-Sales Service**: Igenesis (Shanghai) Co., Ltd.

- **Manufacturer Address**: Floor 3, Building 1, Lane 500, Furonghua Road, Pudong New Area, Shanghai, P. R. China.

- **Email**: support@igenesisbio.com

- **Tel**: +86-21-38016598

Contents

1 About User Manual

1.1 Overview

This section describes how to use the Galaxy Pro user manual which is attached with the instrument gives a detailed description of the use, function and operation of the Galaxy Pro instrument. Before using the instrument, please read this manual carefully and familiarize yourself with contents to ensure the correct use of the instrument the safety of the operator.

Please be sure to strictly follow the instructions in the manual. User could operate the instrument with protective gloves and facial mask after trained.

The illustrations provided in this manual are for example only and please do not use it for other purposes. The graphics, settings, or data in the illustration may not exactly match the actual display you see on the instrument.

1.2 Application Scope of Manual

This manual is suitable for professionals or trained doctors, nurses, experimenters, distributor, agent, after-sale personnel, etc. to read.

● Understand the performance and function of Galaxy Pro instrument.

● Set system parameters.

● Perform daily operation.

● Perform system maintenance and troubleshooting.

1.3 Guide of User Manual

This manual contains ten chapters. The operator can find the corresponding chapters according to the required information.

Section	Reference
1 About Manual	To know the manual
2 System Overview	Intended use and composition of Galaxy Pro instrument
3 Instrument Characteristics	The performance characteristics and parameter of Galaxy Pro

4 Instrument Installation	The installation requirements and steps
5 System Software Functions	The function of the software of Galaxy Pro instrument system
6 Operating Introductions	The daily operation of Galaxy Pro instrument
7 Calibration and Quality Control	The basic requirements of Galaxy Pro calibration
8 Precautions	The operation precautions and limits of Galaxy Pro instrument
9 Service and Maintenance	The maintenance methods of Galaxy Pro instrument
10 Troubleshooting	The causes and solutions of Galaxy Pro instrument failure

1.4 Label

The following signs will be shown in the user manual or instrument:

Sign	Title	Description
	WARNING	If does not follow the warning, it may result in injury to the human body or damage to the instrument. This is the important information for a proper use of the instrument.
	High Temperature	It indicates that a certain area of Galaxy Pro may produce high temperature. Remind users to carefully operate and caution against burns.
	Biohazard	Be cautious in contact with potential infectious and hazardous substances.
	Warning Hands Pinching	It indicates that a certain moving part of Galaxy Pro may cause hands pinching.

Please refer to the following labels position on Galaxy Pro.

Sign	Title	Description
O	Power off	Cut off instrument power supply.
|	Power on	Provide power for instrument.
	Power on button	Press this button to power on the instrument when the main switch is power on,When the button pops up, the instrument will shut down.
	WARNING	Placed on the outside of the instrument.
	High Temperature	Placed near the heating module and warn of potential burn risks.
	Biohazard	Placed near the related modules, when handling biological samples, adhere to the recommended guidelines,requirements,and guidance principles. Ensure sample processing occurs in the specified environment and conditions.
	Warning Hands Pinching	When opening and closing the compartment door, avoid touching it to prevent the risk of getting hands pinching.
IVD	In Vitro Diagnostic	It indicates that Galaxy Pro is an In Vitro Diagnostic (IVD) device.

Figure 1-1Warning Hands Pinching label
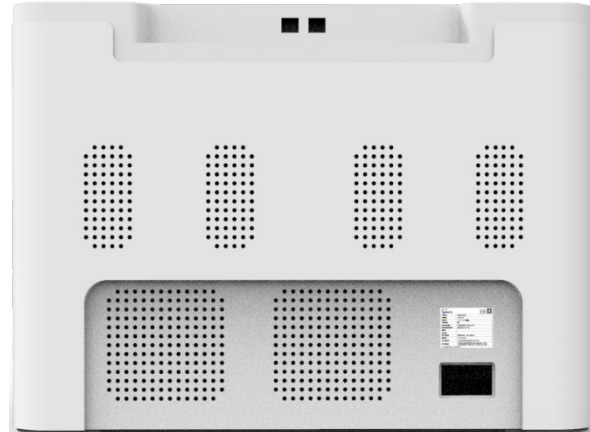
Figure 1-2 Nameplate label

Figure 1-3 High Temperature label

Figure 1-4 Biohazard label

1.5 Security information

This instrument is an electromechanical instrument. If it is not used strictly in accordance with the use manual, it may bring potential hazards to the user, such as electric shock or hand pinching.

● In connection of the power cable, ensure that the power supply is turned off.

● It is forbidden to touch the power switch and power cable with wet hands.

● It is forbidden to unplug and plug the power cable when the instrument is not powered off.

● It is forbidden to clean the instrument while it is not powered off.

● Please turn off the power supply when the instrument is no longer in use.

● To avoid electric shock, the instrument must be grounded properly.

● Please operate the instrument in accordance with the safety instructions.

- It is forbidden to touch the heating module to avoid scalding while the instrument is operating or for a period of time after operation.

- User should keep patients' data complete and confidential in terms of physics, technology and administrative management.

- If users do not follow the given advice, it may cause system damage, data loss or structural failure.

- When user may touch any motion part labeled warning signs indicating that the operator is not allowed to touch it without trained. Please strictly follow the warning sign. Please do not touch the iCassette Tray when Galaxy Pro instrument compartment door opens and closes, or there is a danger of hands pinching.

- Safety masks and protection gloves must be worn when handling toxic, corrosive or infectious substances following the relevant local safety regulations. If a spatter or leakage occurs accidentally, please immediately handle it to protect the laboratory personnel and instruments from contamination.

- Please follow the necessary procedures to clean and disinfect instrument before return it to factory service.

2 System Overview

2.1 Instrument Overview

The Automated Fully Enclosed qPCR Instrument is an automatic fluorescence PCR analysis and detection system with precision temperature control, stable optics system, easy operation, excellent software, etc. The instrument is capable of performing nucleic acid extraction, real-time fluorescence analysis, whole procedure detection. It aims to provide a flexible, safe, quick and contamination-free automated solution for nucleic acid detection in vitro diagnostic.

2.2 Basic Principle

Galaxy Pro Instrument could conduct nucleic acid extraction, purification, amplification and analysis based on real-time polymerase chain reaction (PCR).

Put the reagent kit that loads sample and pre-loaded reagent into the iCassette Tray of the instrument. The heating module heats up the lysis area in reagent box to release the nucleic acid from sample to solution. After magnetic beads adsorption, the extracting solution will be pushed in a physical way to wash area to wash the impurities on magnetic beads. Then, the extracting solution will be pushed in a physical way to elution area to realize nucleic acid extraction and purification by adsorbing the magnetic beads to reagent box via magnetic device. The extracted and purified nucleic acid solution is pushed to PCR area in a physical way and the instrument starts to control the temperature in PCR amplification area and, simultaneously, reads fluorescence signal. Finally, the software could analyze the read fluorescence signal to generate amplification curves, Ct value, etc. automatically.The software also support melting curve analysis function.

2.3 Application Scope

Based on real-time PCR principle and combined with detection reagent, Galaxy Pro is, clinically, intended to extract, purify and quantitatively detect the target nucleic acid (DNA/RNA) from human being samples, such as oropharynx swab, nasopharyngeal swab, genital tract swab, sputum, feces, cervical exfoliated cell. The item of pathogen is one of them.

2.4 Structure and Components

Galaxy Pro mainly consists of extraction module(2 sets),PCR module(2 sets),iCassette tray(2 sets) and system software (Version: V1.3).

Extraction module is composed of mechanical motion unit, temperature control unit and magnetic unit.

PCR module is composed of optics, temperature control unit, electric system and relative software functions.

iCassette tray is used for loading reagent kit.

System software is the control software on PC.

The instrument structure is as shown in figure 2-1(The pad in following figure is only an example.).

Figure 2-1 Galaxy Pro Structure

Galaxy Pro e-ports are as shown below:
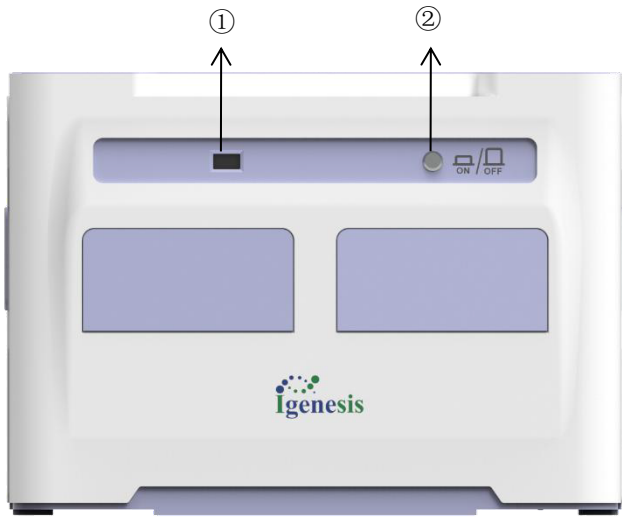
Figure 2-2 Front view

Figure 2-3 Back view

① LCD,can show the instrument number

② Power on/off button
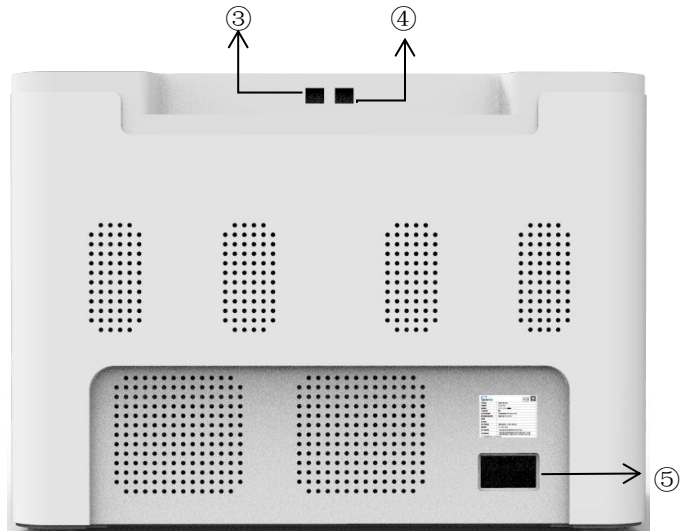
③ CAN IN:Cascade Input Port

④ CAN OUT: Cascade Output Port

⑤ Main Power Switch
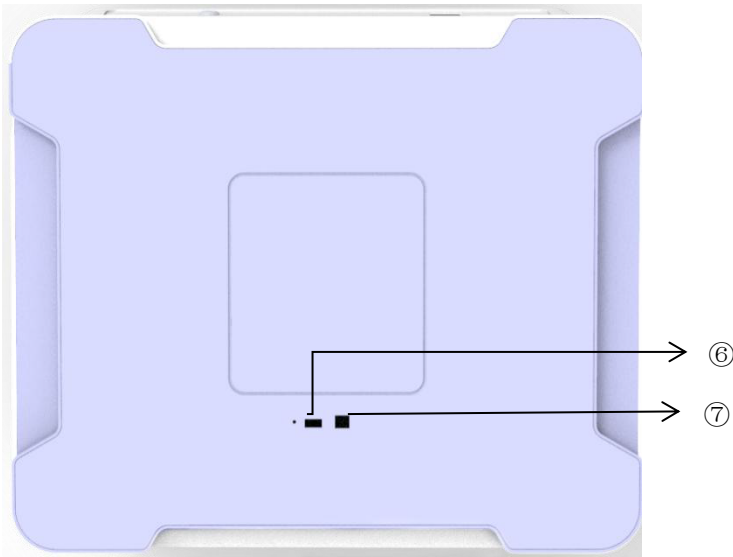
Figure 2-4 Top view

⑥ USB 5V 2A：Standard USB Type-A charging port, providing 5V 2A charging capability

⑦ DATA：Standard USB Type-B Electronic Data Exchange Interface:connecting instrument to PADs (tablets) or PCs..

Data Storage Format: The data storage format adheres to the standard TXT file format.

Data Types:The exchanged data includes device-specific data and non-sensitive detection data.

Transmission Protocol: private protocol,this protocol ensures seamless data exchange and coordination between the software and the instrument.

2.5 Accessories

iCassette Tray: It is used for loading reagent kit.
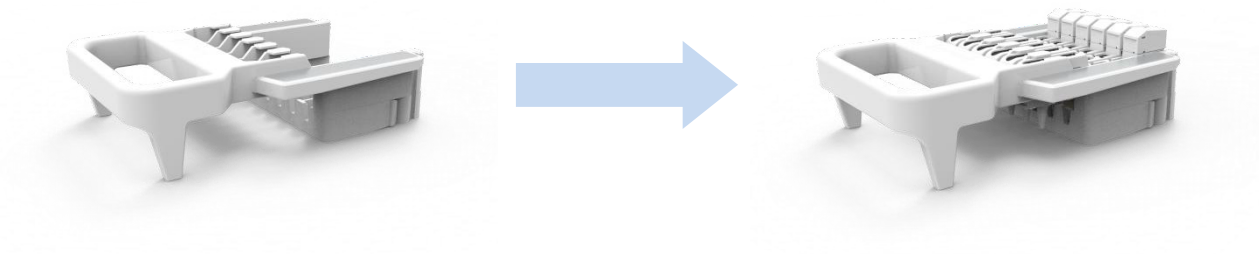
Figure 2-5 iCassette Tray

Reagent Kit: It is a disposal detection consumable and is charged. Please contact the after-sale service or agent to purchase the reagent kit.

⚠ **Biohazard**: Please keep the reagent kit properly. The improperly preservation may cause regent invalidity. Please do not disassemble the reagent kit and handle it with care according to the local regulation and lows.

Communication Cable: It is recommended to use the communication cable by Igenesis.

Power Cord: Please use the power cord provided by Igenesis.

2.6 Running Environment

Galaxy Pro's running environment:

● Hardware: 32-bite MCU Microprocessor;

● Network: Without connection;

Pad or PC running environment:

● CPU: 2GHz or higher;

● Memory: 2GB or higher;

● Hard Drive: 2GB or higher:

● Software Configuration: Window 10, 64-bite;

● Network: The pad or PC connected to instrument could access to wired (with internet port RJ-45, bandwidth 10M or higher) or wireless (Wi-Fi IEEE 802.11, bandwidth 10M or higher) LIS network.

3 Instrument Characteristics

3.1 Overview

This section introduce the Galaxy Pro instrument characteristics and key parameters.

3.2 General Specifications

▶ **Instrument Specification:**

Dimension: 550mm(L) × 480mm (W) × 400mm (H);

Weight: 45kg;

▶ **Application Environment:**

Temperature: 15℃-35℃;

Relative Humidity: 20%-85%RH;

▶ **USB Port:**

There is a USB port in instrument functioned to connect to a computer.

3.3 Throughput

The instrument owns 12 throughputswhich can be expanded to 96 maximally via 8 instruments cascade.

3.4 Fluorescence Channel

The instrument possesses 7 channels and dyes like FAM、HEX/VIC、TAMRA/NED、ROX/TEXAS RED、CY5、CY5.5、AMCA is available. Please see details in the following table.

Channel No.	1	2	3	4	5	6	7
Excitation Filter	460nm	525nm	543nm	571nm	624nm	675nm	350nm
Emission Filter	525nm	564nm	584nm	624nm	675nm	710nm	460nm
Suitable Dyes	FAM	HEX/VIC	TAMRA	ROX/ TEXAS RED	CY5	CY5.5	AMCA
Light Source	white LED						UV LED

3.5 PCR Temperature Parameters

▶ **PCR Temperature Range:**
   5℃～99℃

▶ **Temperature Control Precision:**
   ≤0.5℃

▶ **Temperature Uniformity:**
   ≤1℃

▶ **Max. Heating Rate:**
   ≥7.0℃/s

▶ **Max. Cooling Rate:**
   ≥5.5℃/s

4 Instrument Installation

4.1 Overview

This section describes the installation process and precautions of Galaxy Pro.

In order to ensure the proper operation of the instrument after installation, the installation and initial settings at delivery of Galaxy Pro needs to be performed by authorized personnel of Igenesis.

⚠️ **Warning**: Installation by personnel unauthorized from Igenesis may cause damage to the instrument so do not install Galaxy Pro instrument without the presence of Igenesis authorized personnel.

4.2 Installation Requirements

The operator must ensure that the following requirements of space, power supply and environment are met before installation.

4.2.1 Space Requirements

- The instrument installation must meet the following requirements:

- The space between instrument left and right sides and the wall should be greater than or equal to 28cm.

- The space between the instrument back and the wall should be greater than or equal to 10cm.

- The Galaxy Pro instrument shall be placed on a stable and horizontal platform with a bearing capacity ≥70 kg.

- The instrument shall not be placed in the strong electromagnetic disturbance environment.

- The instrument shall not be placed in the air outlet.

- The instrument shall not be exposed to a direct sunlight.

- The platform length shall be greater than or equal to 500cm when instruments cascade.

- Please do not place the device in a position where it is difficult to disconnect the device.

4.2.2 Electrical Requirements

- Power Voltage: 220VAC±10%；

- Overvoltage category:II；

- Power Frequency：47~63Hz;

- Input power：≥900VA for a single instrument run.

- The power shall be grounded properly.

- The instrument shall not use the same power supply with the high-power and electromagnetic disturbance devices.

- Please evaluate the electromagnetic environment before using the instrument.

- Please take protection measures if use the instrument home because it may generate radio interference.

> ⚠️ **Warning**: In order to prevent electric shock, the Galaxy Pro instrument must be connected to a three-pin grounded socket conforming to safety standards. The power cable should be three-core and matched with the instrument.

4.2.3 Electromagnetic Compatibility

The emission and disturbance immunity of Galaxy Pro instrument is in conformity with IEC 61326-2-6.

- The instrument shall be used in lab or the area where the electromagnetic environment is in control. Please do not use the instrument besides the strong radiation source (e.g. unshielded RF) because it may disturb instrument running.

- Please evaluate the electromagnetic environment before using the instrument.

- The instrument is designed and tested according to Class A equipment in CISPR 11 IDT. The instrument may cause radio interference at home environment and the protective measures are required.

- The manufacturer is responsible for providing electromagnetic compatibility information of instruments to users.

- The user is responsible for ensuring the electromagnetic compatibility environment of the instrument so that the instrument can run normally.

4.2.4 Environmental Requirements

The environment where the instrument runs shall meet the following requirements:

- Operating temperature: 15～35℃;

- Relative Humidity: 20%～85%;

- Atmosphere Pressure：85.0kPa～106.0kPa;

- The environment should be dust-free and well ventilated for indoor use.

- The environment should not be disturbed by the strong electromagnetic.

- User shall ensure that the environment is in conformity with the electromagnetic compatibility requirements.

- Please do not place anything save the holder and pad.

- Pollution degree of the intended environment:Level 2.

> ⚠ **Warning**: User shall ensure that the instrument is operated in the required environment so as to make sure the instrument runs in a good condition.

4.2.5 Fuse Requirements

The fuse used in instrument is T10AL 250VAC 5*20mm.

> ⚠ **Warning**: Please replace the fuse with an equal one, or it may damage the instrument.

> ⚠ **Warning**: Please unplug the instrument before replacing the fuse to avoid electric shock.

4.2.6 Computer Requirements

The computer matched to the instrument shall meet the following requirements

- Dominant Frequency: 2GHz or higher;

- Memory: 2GB or higher;

- Hard Drive: 2GB or higher;

- Operation System: Windows 10 64-bite;

- Software Installed: Microsoft.Net Framework 4.5;

- Computer system time is right.

- Please exit the computer dormancy mode while the instrument is running.

- Please keep the display on while the instrument is running.

- Please set screen protection for the computer so as to the data cannot be viewed by the unauthorized person.

- Please install the professional antivirus software, data security defense software and network security protection software and regularly upgrade them.

- Please do not connect the computer to the network at risk.

- Please close the account, communication port, shared file, service, etc. Of the non-medical use.

- Within the instrument life cycle, user could contact Igenesis after-sale for any cyber security problems. If necessary, Igenesis could send the technical staff for a site service.

> ⚠ **Warning**: It is strongly recommended that user should install the professional antivirus software, data security defense software and network security protection software to avoid the experiment data is acquired in an illegal way.

4.2.7 Bar-code Scanner

Bar-code Scanner is purchased by the users.

Instructions for using a bar-code scanner:

- Connect the bar-code scanner to the PC,install the necessary driver software as required by the scanner.

- Before scanning, make sure your input method is set to English.

- When using the bar-code scanner, hold it at a 30° angle relative to the bar-code for optimal reading. Avoid scanning directly at a 90° angle, as it may not result in successful scanning. Ensure that the scanner aligns properly with the bar-code, and you'll hear a confirmation sound when the scan is successful.

4.3 Installation Process

4.3.1 Instrument Placement

After the arrival of the instrument, please carefully check whether the package of the instrument has physical damage. If there is any damage, please immediately inform the after-sales service or local agent of Igenesis.

After confirming that there is no external damage, open, carry, and place the instrument by following the below requirements:

- During carrying the instrument, please protect it from impact and collision.

- During carrying the instrument, please keep it upright.

- Before taking out the instrument, please keep the package stable and upright.

- Open the package and take out the instrument with care.

- Place the instrument on the lab platform according to "4.2 Installation Requirements"

- If needs to move the instrument after placed, please move it slowly with care.

- Keep the package well in order to need it again when carries the instrument.

4.3.2 Unpacking Steps

Please check out the packing list as blew.

No.	Name	Quantity
1	Automated Fully Enclosed qPCR Instrument	1
2	Galaxy Pro User Manual	1
3	Quick Guide	1
4	Warranty Card	1
5	Certificate of Conformity	1
6	Power Cord	1
7	iCassette Tray	2
8	PCR Tube Installation Tool	2
9	System Software（USB Flash Drive）	1
10	Communication Cable	1
11	Communication Accessories(IN/OUT)	2
12	Network Cable	1
If there is any shortage or damage, please contact the after-sale service.		

4.3.3 Instrument Installation

The instrument shall be installed as the following steps.

● Please place the instrument according to "4.3.1 Instrument Placement";

● Please make sure that the power grid where the instrument connects is 100-240VAC   and the socket is a one-phase three-pin.

● If only install one instrument, the power of the grid shall be greater than one equal to the single instrument's. Please refer the instrument power to "4.2.2 Electric Requirement".

● If install more than one instruments, the power of the grid shall be greater than one equal to the total power of instrument's.

- Please close the AC power switch, insert the power cable in the package into the jack and than plug the instrument.

- Please make sure the IN and OUT port is properly connected.

- Connect the communication cable to USB Type-B port in instrument and connect the other side to the computer's USB-C port (Please ensure the port is well functioned.).

4.3.4 System Software Installation

Please follow steps below to install the system software.

- Take out the USB flash drive and insert it into the computer.

- Find the "Ecantools" driver software installation package, double-click "Ecantools-Setup.exe" and follow the installation prompts to install it. Igenesis will provide all services of the third-party ready-made software within Galaxy Pro system life cycle.

- Copy "**Galaxy Pro controller software" file** to the PC,send the "**Galaxy Pro.exe"** to the desktop shortcut**,** and double-click the "Galaxy Pro controller" icon to open the software. At this time, the software installation is completed.

- The system software upgrade is conducted by Igenesis staff or the personnel authorized by Igenesis.

4.3.5 Instrument Startup and Test

Please start and test the instrument after instrument and system software installation.

- Press the "Main Power Switch" key at the back of the Galaxy Pro instrument. When the "Switch" is on, the instrument is turned on.

- Press the "Power Switch" key at the front of the instrument to turn on the instrument.

- Double-click "Galaxy Pro" on desktop to enter software interface.

- Please use Admin account (Username: Admin, password: 123456) to log in the software for the first login.

- After login, the instrument will automatically perform self-checking.

- During and after self-inspection, if there is no abnormity, the user can use it normally. If there is abnormity, please contact the after-sale service.

4.3.6 Instrument Shutdown

Please shut down the instrument by following the below steps.

- Log out the system software.

- Press instrument "Power Switch" to shut it down, the indicate light is off.

- Please off the "Main power Switch" of the instrument if it is not used for a long time.

4.3.7 Instrument Cascade

It is available that 8 Galaxy Pro instruments can be connected each other maximally. 8 instruments could run simultaneously. Please follow the steps below to complete instrument cascade.

- Please pace the instruments to be cascaded on the lab platform form left to right according to the single instrument placement requirements.

- Connect each instrument's power cord to power grid according to the single instrument power cord connection requirements.

- Connect the first instrument to the computer with communication cable.

- Take off the first instrument's rear OUT connector and connect one end of network cable to the OUT port while the other end is connected to the second instrument's IN port so connect the rest of the instruments in same way.

- Please keep the IN and OUT connectors with care because they will be reused when run the instrument singly or transport it.

- Open and log in the system software, click "Setting"--> "Device Cascades" function key and the system software will prompt "Whether to initialize cascade?".

- Please ensure that all instruments are turned off and click "Yes". The system software displays device cascade prompt window and user could follow the software prompts to operate.

- After the instruments are connected, the connection status on interface will be changed from "Uninstall" to "Available".

- If user needs to change the instrument position or instrument, the instrument cascade shall be re-connected according to the above first 8 steps.

4.4 Storage and Transportation

4.4.1 Storage

If the instrument is unpacked, please store it as the following requirements.

● Ambient Temperature: - 20℃-50℃.

● Relative Humidity: 20%-85%, non-condensing.

● The instrument shall not be stored in the environment with corrosive gas.

● The instrument shall not be exposed to the sunlight.

If have any questions, please contact the after-sales service personnel.

4.4.2 Transportation

The product should be transported according to the following requirements

● Please close compartment door.

● Please take off the instrument power cord and communication cable.

● Please disinfect the instrument.

● Please pack the instrument the original package.

● Please keep the instrument package stable with materials against the package two sides so as to avoid the package impact and collision.

● The transport temperature and humidity requirements are same to storage's.

● The transport temperature atmosphere pressure：85.0kPa～106.0kPa.

If have any questions, please contact the after-sales service personnel.

5 System Software Functions

5.1 Overview

This section systematically introduces the functions of system software so that user could operate instrument properly.

5.2 Login Interface

After double-click "Galaxy Pro.exe", the login interface is shown in figure 5-1.

Figure 5-1 Login Interface

⚠️ **Warning**: Please enter the right user ID and password.

5.3 Initial Interface

After entering user ID and password and logging in the system software, the initial interface is as shown in figure 5-2.

Figure 5-2 Initial Interface

The initial interface have the following function keys:

【Open/Close】、【Run】、【Init】、【Tool】、【Date】、【Device】、【Switch】、【Quit】

5.4 Menu and Function

5.4.1 Open/Close

If the compartment door is closed, click Open to open the compartment door while if is open, click Close to close the compartment door.

When opening and closing the compartment door, avoid touching it to prevent the risk of getting hands pinching.

5.4.2 Run

- Click the "Run" button and enter the sample information to execute the corresponding program.

- When the system is running, the user can also click the "Stop" button to stop the current program processing according to needs.

- The Galaxy Pro instrument will perform a hardware reset after the user stops it. Depending on the procedure being performed, the return time may vary. After the homing is completed, the system will return to the Initial   interface as shown in Figure 5-2 .

> ⚠️ After stopping midway, the Galaxy Pro instrument will not retain any data, and the current reagents cannot be used again. After each experiment, there is a large amount of amplification product in the reagents, which should be processed as soon as possible according to relevant regulations to avoid contaminating the laboratory and the instrument. Used disposable reagents must be disposed of in medical waste bins and are not allowed to be thrown into the public waste system. The user must confirm the impact before stopping the program.

5.4.3 Init

Click the "Init" button to restore the position of each mechanical structure in the instrument to its initial position. The software will pop up to prompt initialization information;

5.4.4 Data

- Click the "Data" button in the menu bar to display all historical reports of this instrument. Select the report you need and double-click to open the historical report.

- When the PAD or PC has insufficient memory, the system will remind the user that "the disk space is low xxxMB , please clean up in time"; Users can backup and save test reports (the entire software can be saved) to prevent accidental loss or damage.
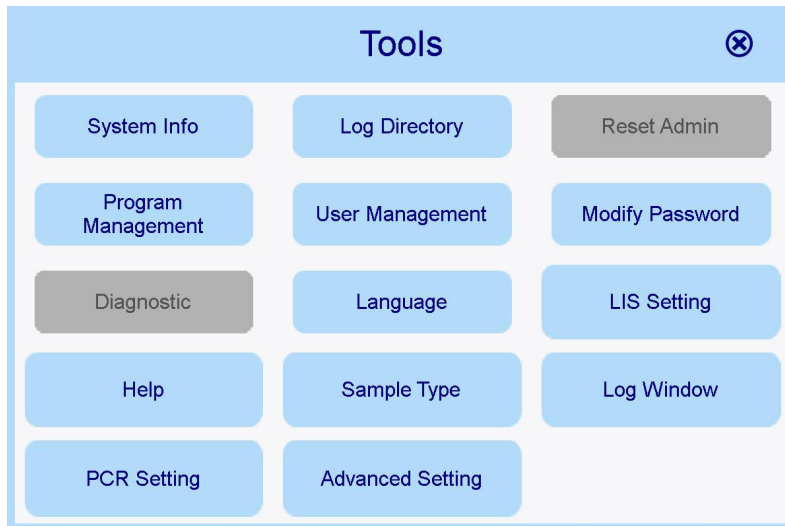
Figure 5-3 Data Interface

5.4.5 Tool

Figure 5-4 Tools Interface

5.4.5.1 System Information

The system information displays the instrument SN that belongs to the connected instrument and the current software version. The unconnected instrument SN is empty.

5.4.5.2 Log Directory

● Clicking the "Log Directory" button will open the folder where the Data Log is stored, showing all the logs of this instrument.

● The Data Log folder contains the igenesis.log file that records key information about each daily use session. You can click to view according to the log date.

5.4.5.3 Reset Admin

The administrator password reset feature is only available with superuser privileges.

5.4.5.4 Program Management

Requires administrator permissions.

● **Number**: Program code in hexadecimal format, must be unique..

● **Program name**: Corresponds to the program file name and can be repeated.

● **Add**: Add a new program from the specified path, and the software will copy the program to the installation path.

● **Delete**: Delete the program file of the currently selected line.

The mapping between barcodes and programs is stored in the software configuration file.

Supports up to 1024 programs; exceeding this limit will result in an error popup.
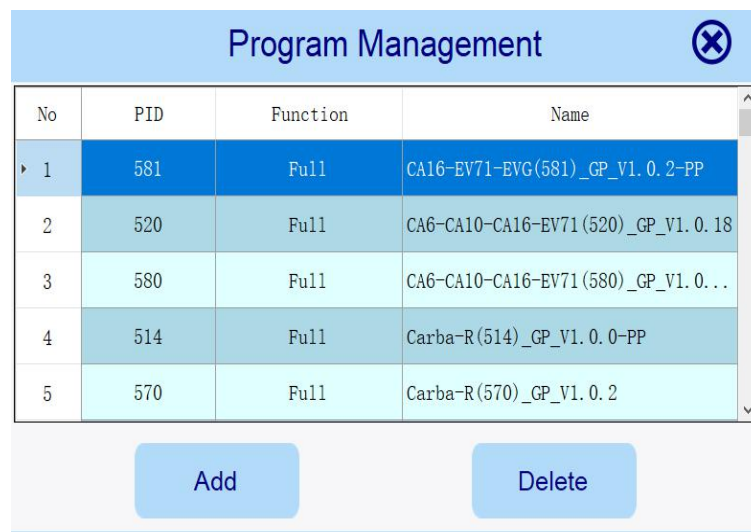
Figure 5-5 Program management

5.4.5.5 User Management

Click "User Management" and the "User Management" interface as shown in figure 5-6. On the left is a list of existing users, and on the right are the function buttons for adding, deleting, and resetting user passwords .
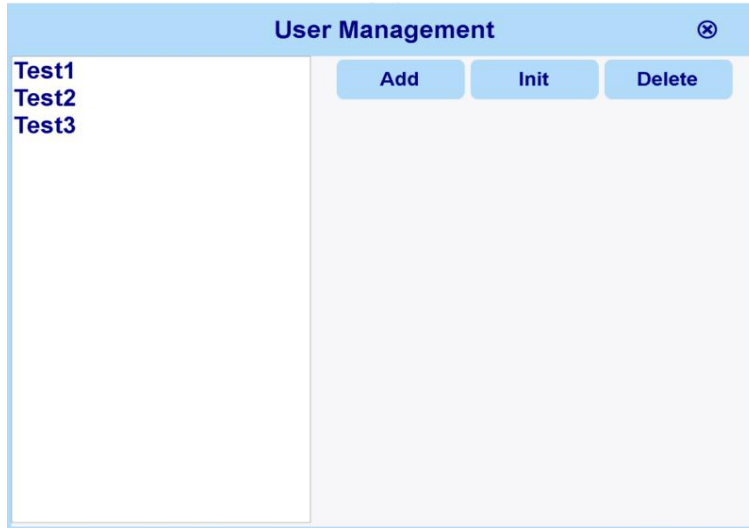
Figure 5-6 User management interface

- **Add user**: Click the "Add" button, the user information input box will be displayed (for example, if we create a new user User1, the user name cannot be empty, cannot be Admin, cannot be Pro_IGS, and cannot have the same name as the existing user name), enter the password twice in a row , must be consistent and cannot be empty (Figure 5-7) , click the "OK" button and User1 will be successfully inserted into the left list (Figure 5-8) .
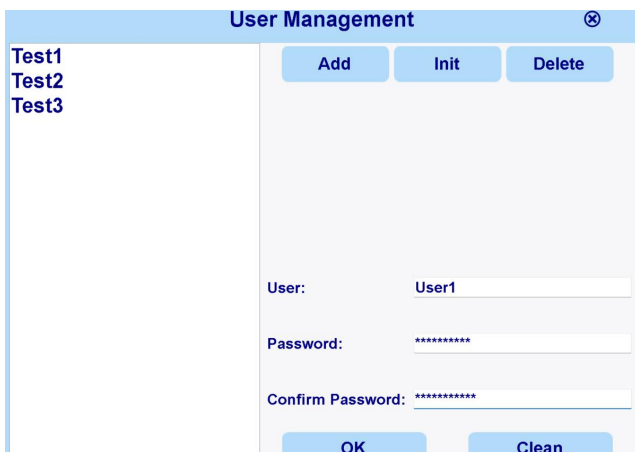
Figure 5-7 User addition interface   Figure 5-8 User added successfully
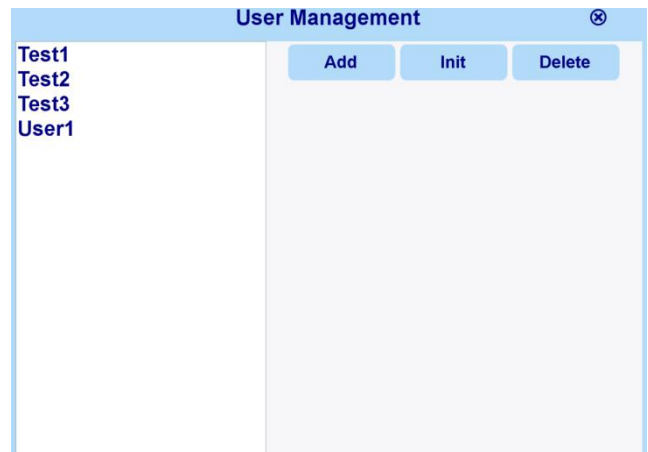
- **Reset user**: Click the "Init" button. The Admin administrator account can reset the Common user password (Figure 5-9) . The reset password is: 123456 (Figure 5-10) ;
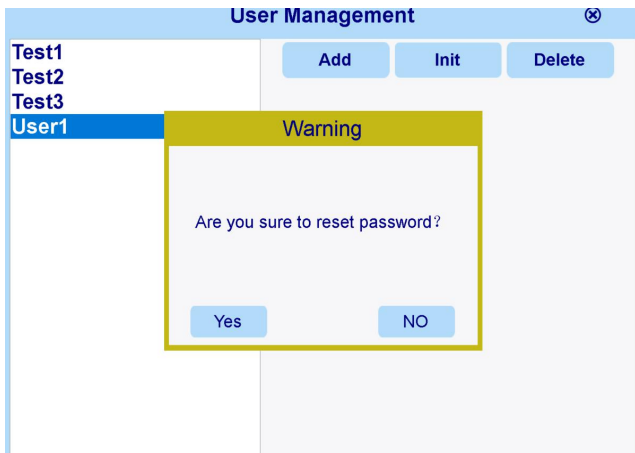
Figure 5-9 User reset interface
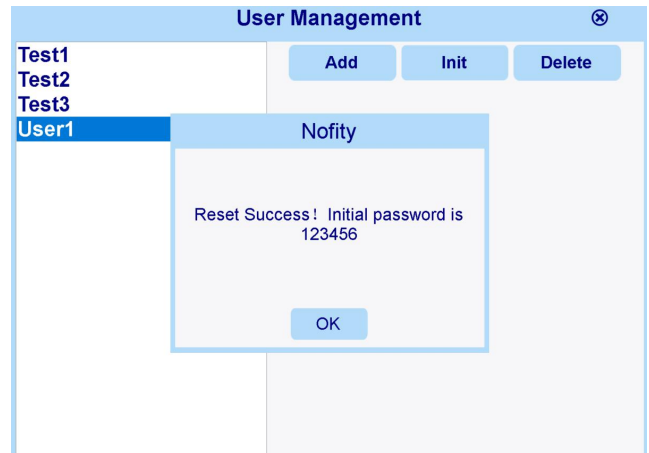
Figure 5-10 User reset successfully

- **Delete a user**: Click the "Delete" button, and the system will confirm to the user whether to delete the user (Figure 5-11) .
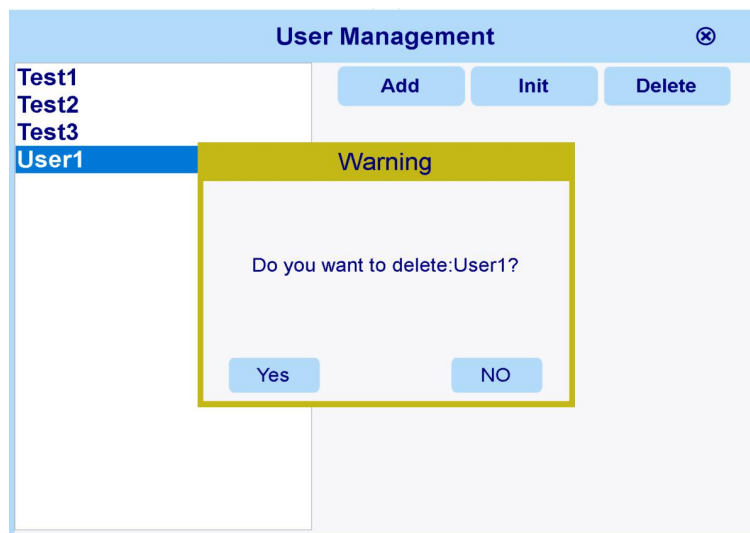
Figure 5-11 Delete user interface

The Galaxy Pro system is divided into three levels: Common user, Administrator and Super user. The default setting for system software is Admin . Illegal users other than super user who are not in the user management list cannot log in.

5.4.5.6 Change Password

Click "Change Password" , and the following password change interface as shown in figure 5-12:
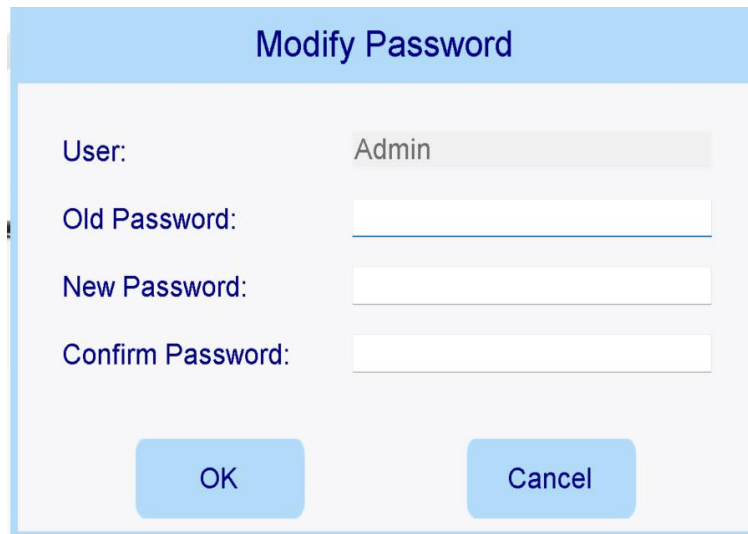
Figure 5-12 Password modification interface

- **User**: Displays the username currently changing the password.

- **Old password**: Enter the oldl password.

- **New Password**: Enter the new password. The password cannot be empty.

- **Confirm Password**: Enter the new password again, which must be consistent with the previous password; the user password setting must meet the conditions of alphanumeric characters plus special characters and at least 6-20 characters.

- **Confirm**: After the input is completed, the password is successfully modified, and it will also be saved to the file where the user information is stored, and finally the window is closed.

- **Cancel**: Cancel the password change, clear the contents of all input boxes in the window, and close the window.

5.4.5.7 Diagnosis

Enter the diagnostic interface, as shown in figure 5-13. Requires super user privileges and the instrument is idle.
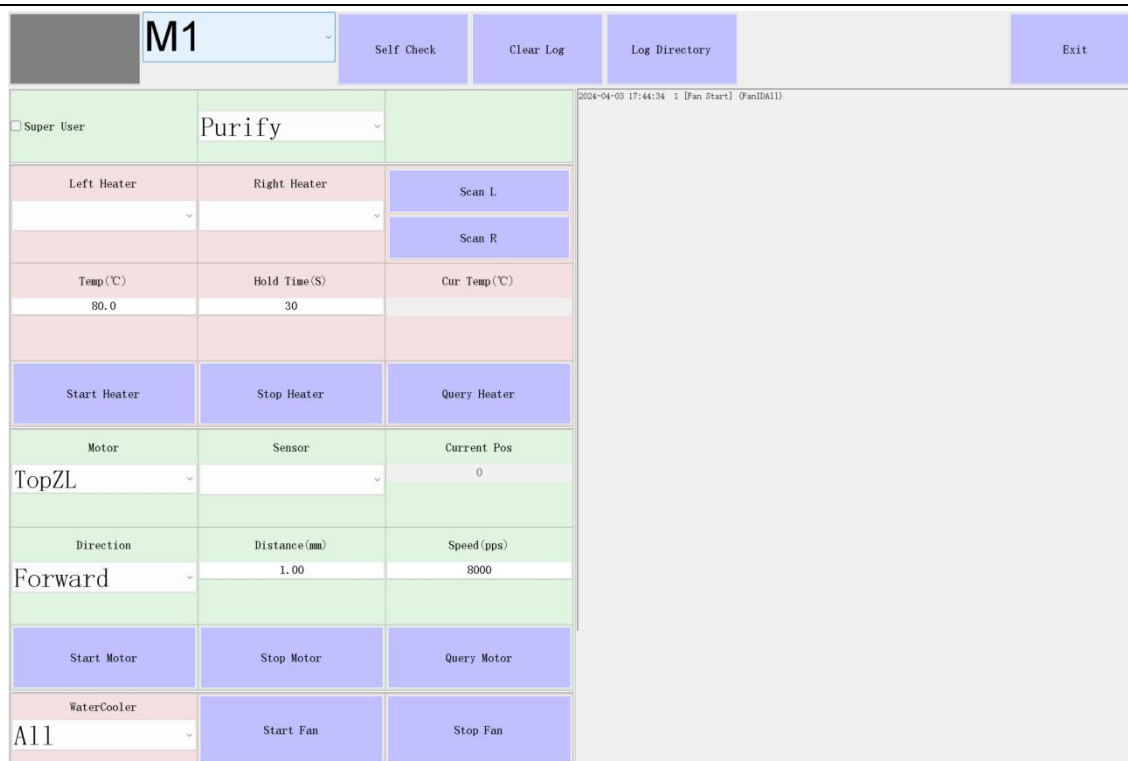
Figure 5-13 Diagnosis interface

⑴ The connection status of the instrument, gray means not connected, green means connected.

⑵ Shortcut function keys:

M1: M1-M8 instruments can be selected.

Self-Check: Enter the self-check interface to perform self-check on the lysis temperature control , elution temperature control, motor, code scanning, PCR and other modules .

Clear log: clear the diagnostic information in the white area on the right.

Log directory: Display the folder where diagnostic information is currently stored.

Exit: Exit the diagnostic interface.

⑶ **Super user**: can make the motor ignore the restriction rules.

⑷ **Scanning L/R**: Control the scanning engine to read QR codes.

⑸ **Purify** : The drop-down box allows you to select three options (Purfy/Elution/PCR).

⑹ Temperature control diagnosis:

Temp: Set the temperature of Heater in ℃.

Hold time: Set the Heater's hold time.

Current temp: Displays the current temperature of Heater.

Start Heater: Start the heating function of Heater.

Stop Heater: Stop the heating function of Heater.

Query Heater: Query the temperature value of Heater.

（7）Motor diagnostics:

Motor: Select the Motor ID of the current operation, total 1 to 16 motors.

Sensor: Select the sensor position, range Origin (the sensor corresponding to the motor can be set in the factory version software), If the sensor selects a null value, the motor can be moved according to the distance.

Current Pos: The current position of the motor.

Direction: The direction of motor movement, range: Forward, Back.

Distance (mm): The distance the motor moves, unit mm.

Speed (pps): Speed of motor movement, with a range of 500-16000.

Start motor: Start the motor movement function.

Stop motor: Stop the motor movement function.

Query Motor : Query the status of the motor.

5.4.5.8 Language Setting

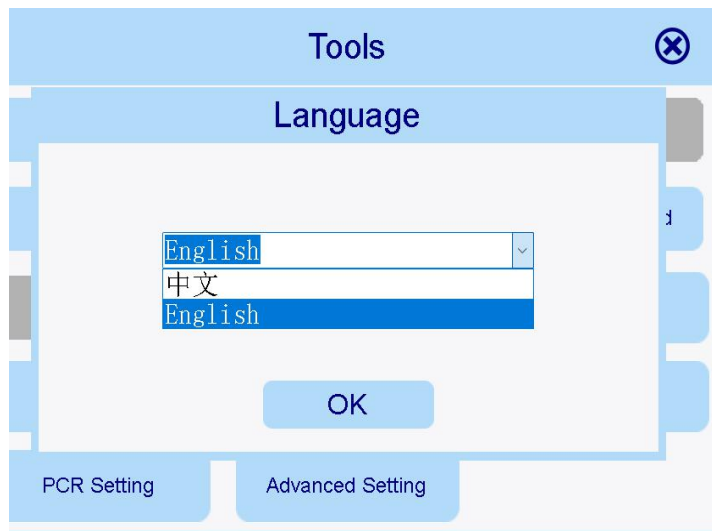User could set system language as Chinese and English, as shown in figure 5-14.

Figure 5-14 Language Setting interface

5.4.5.9 LIS Setting

Click "LIS Setting" , and the LIS Config interface as shown in figure 5-15
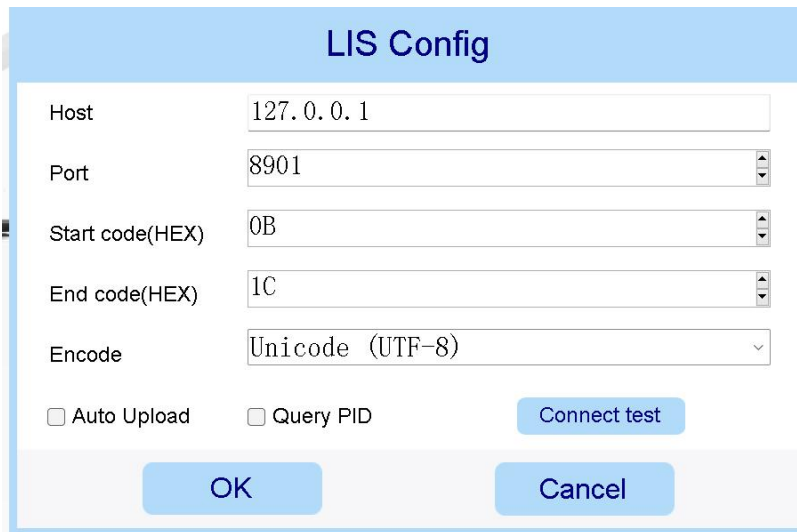
Figure 5-15 LIS Setting interface

- **Host** : Default 1 27.0.0.1 , host IP address can be added , cannot be empty;

- **Port** : Default is 8901 , port can be added;

- **Start code (HEX)** : Default 0B;

- **End code (HEX)**: Default 1 C ;

- **Encode**: Default Unicode (UTF-8) ;

- **Connect Test**: When entering the correct host IP address, click the "Connect Test" button, and the interface shows that the connection to the IS system is successful; when entering an incorrect host IP address , click the "Connect Test" button, and the interface shows the connection to the LIS system failed;

- **Auto upload**: After successfully connecting to the LIS system, check "Auto upload", and then click the "OK" button,after running the program, the data will be automatically uploaded through the LIS server ; when "Automatic upload" is not checked, you can enter the historical data interface with manually upload the selected data . If the upload is successful, you can check the upload status of the corresponding data on the historical data list interface;

- **Query PID** : After successfully connecting to the LIS system, check "Query PID" , and then click the "OK" button,when running the program, enter the correct sample information (ID) and the corresponding patient information will automatically pop up. Enter The error sample information (ID) interface prompts "No patient information found"; when "Query PID" is not checked, the patient information will not be recognized when running the program**.**

5.4.5.10 Help

Click the "Help" button to view the Quick operation guide and User manual.

5.4.5.11 Sample Type

User could enter the new sample information like oropharyngeal swab and click "Add". The sample type is successfully saved and can be viewed in the "List".

5.4.5.12 Log Window

User could view the operation records, including login, logout, initialization, stop, exit, program name run, reagent kit QR code and experiment completion.

5.4.5.13 PCR Setting

The PCR setting allow users to compile PCR programs.

5.4.5.13.1 Open The PCR Setting Interface

Click "PCR Setting" , and the PCR setting interface as shown in figure 5-16:
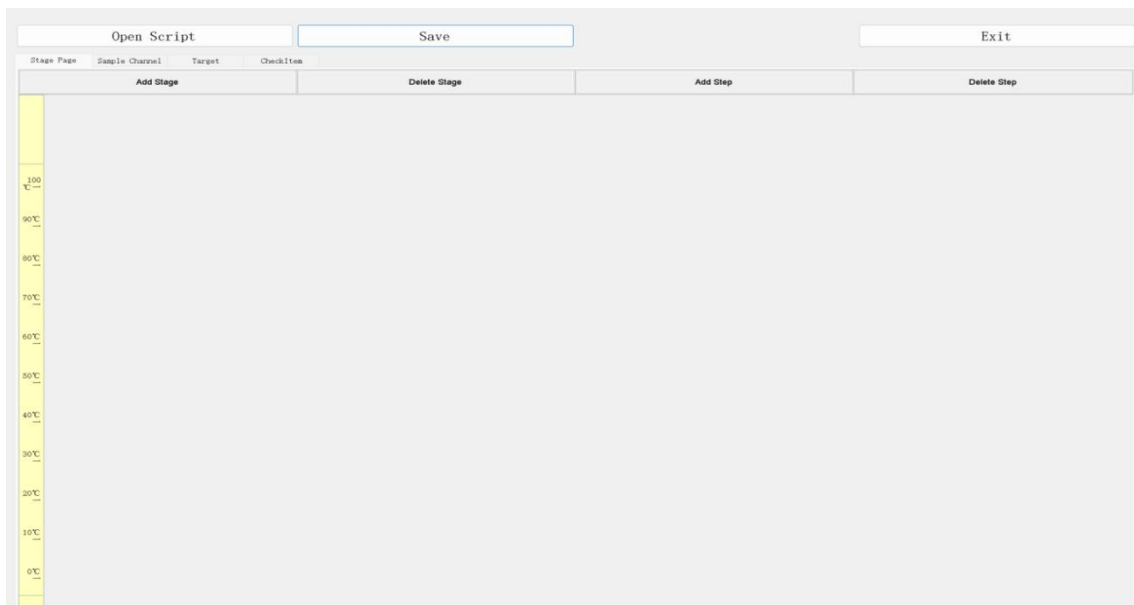
Figure 5-16 PCR Setting interface

- **Open Script**: Select and open an existing script file. If the script in the current table have been modified, it will give a prompt whether to save them. When the script is executing, clicking is not allowed.

- **Save** : See 5.4.5.13.3 ;

- **Stage page** : See 5.4.5.13.2 （1）;

- **Sample channel** : See 5.4.5.13.2 （2）;

- **Target** : See 5.4.5.13.2 ;

- **Check item** : See 5.4.5.13.2 ;

5.4.5.13.2 Edit PCR program

（1） **Program setting:**
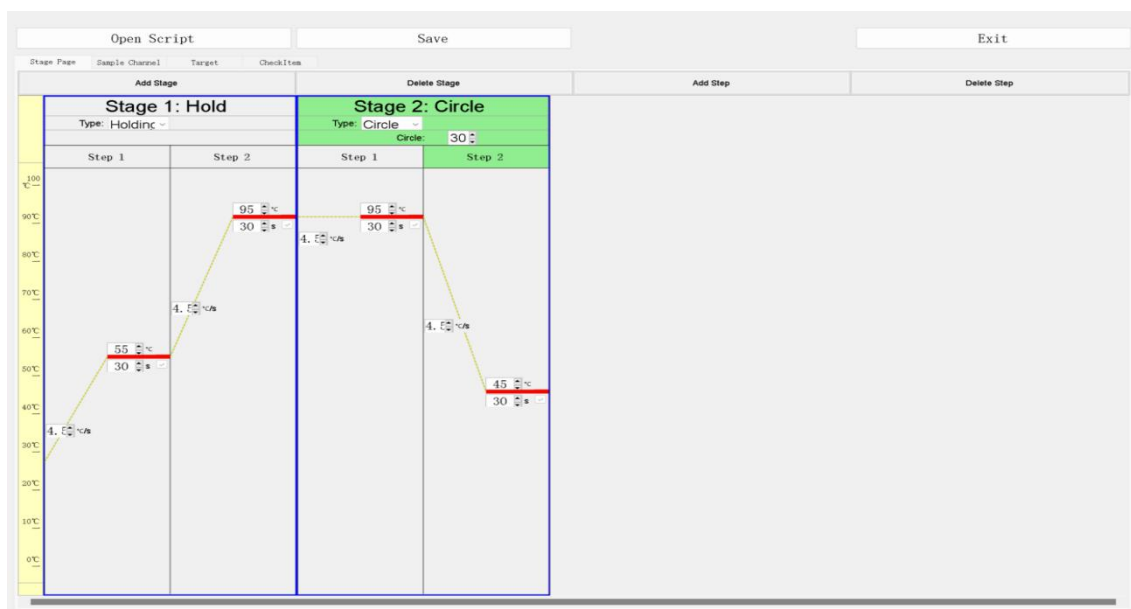
Figure 5-17 PCR program setting interface

The green area in the figure represents the currently selected program stage and program step, and the thick red line can be dragged; Check the constant temperature stage to indicate whether collect the PCR fluorescence data.

  Add Stage : Add a new stage after the currently selected stage. Stage will be classified into four types: Hold, Cycle, Melt, and Probe check. Can be switched at "Type". The maximum number of stage is 10.

  Delete Stage : Delete the currently selected stage.

  Add Step : Add a new step after the currently selected step. The maximum number of steps in a stage is 10.

  Delete Step : Delete the currently selected step. If there is only the last step in the selected stage, it can not be deleted.

Cycle : The number of cycles can be set.

Melt : You can set the melting curve function .

⑵ **Sample channel setting:**

Users can select channels according to the PCR reagents to be added:

Figure 5-18 PCR fluorescence channel settings interface

Target:

Users can add new targets based on the fluorescence channel of the PCR reagent to be added:
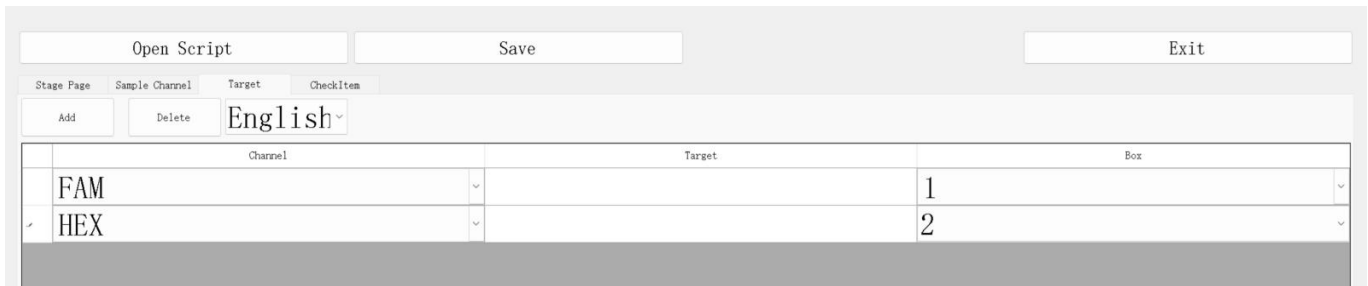
Figure 5-19 PCR target setting interface

Check Item:

Set the negative and positive interpretation according to the PCR reagent manual:
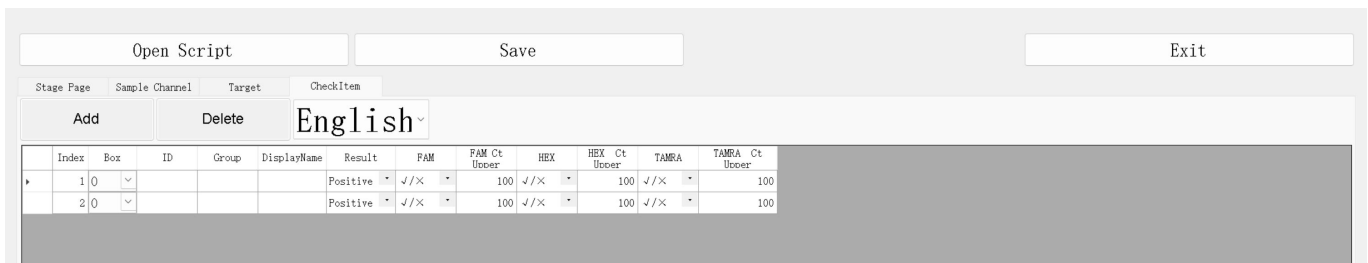
Figure 5-20 Result interpretation setting interface

5.4.5.13.3 Save

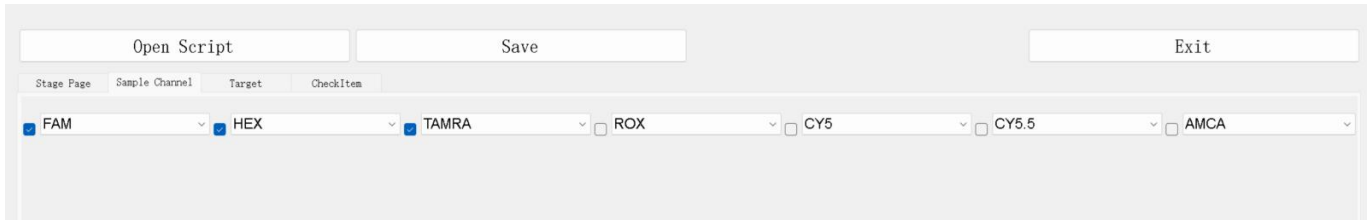Save the currently edited PCR processing program. Save the script into a new program. The script save interface as shown in Figure 5-21 :
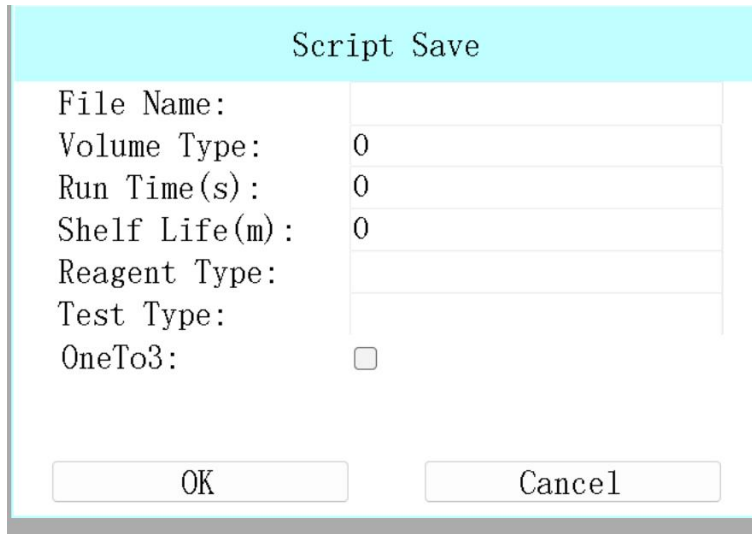
Figure 5-21 Script save interface

- **File name** : The script name of this program.

- **Volume Type**: PCR reaction volume.

- **Run Time(s):** Execution time of the program, unit: seconds.

- **Shelf Life(m):** Validity period of the program, unit: months.

- **Test type** : Classification of this test.

- **Reagent type**: Full process, PCR, Extraction.

- **One to 3:** Type of the iCassette, checked if you use this type of iCassette.

5.4.5.13.4 PCR Program Petting

Enter the "Program Management" window at the "Tool" main interface of the Galaxy Pro software , click the "Add" button in Figure 5-5 , enter the path C:\Users\Desktop\Galaxy Pro_UI_VX.XX\Script and select the saved PCR program script , double click this script add the PCR program to this column (as shown in Figure 5-4). After the setting is completed, close the window, the PCR program setting is completed.

5.4.5.14 Advanced Pettings
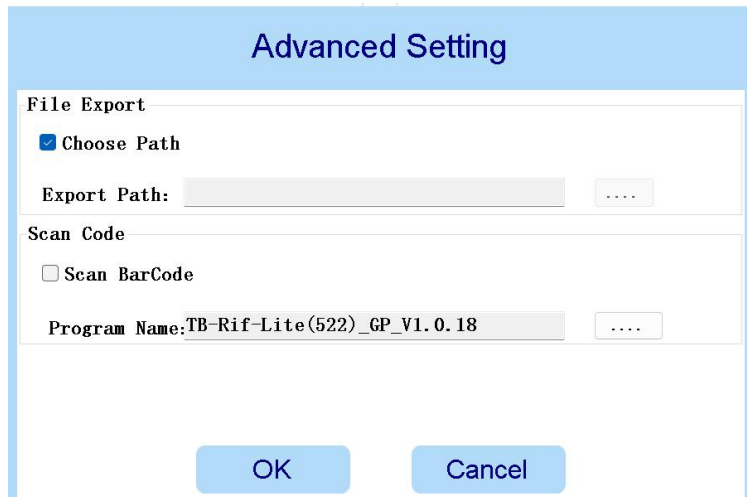
Figure 5-22 Advanced settings interface

- **File Export**: Users can export the data and choose the path to save.

- **Scan code**: When running the test kit, users can choose a program and run it without a QR code.

5.5 Software Features

5.5.1 Compatibility

- The Galaxy Pro system software requires Windows 10, 64-bit, or compatible operating systems.

- The Galaxy Pro system software is exclusively designed to support the Automated Fully Enclosed qPCR Instrument (model: Galaxy Pro).

- To run the Galaxy Pro system software, users need to configure the 2.10 runtime environment in advance.

Security software compatibility list		
Security Software	Vendor	Operating Environment
360 Antivirus	Qihoo 360	Windows 10 OS
Windows Defender Firewall	Microsoft	Windows 10 OS

5.5.2 Reliability

If the system encounters a power failure during operation, after troubleshooting, restart the Galaxy Pro host will restore normal operation; if the system experiences PAD/PC power failure during operation, after troubleshooting, restart the PAD/PC ,Log in to the Galaxy Pro system software again and the system can resume normal operation.

Users are advised to manually back up "PcrData" to prepare for data recovery in case of unexpected situations.

Data backup and recovery steps:

- **Data backup**: Open the Galaxy Pro system software installation package , select the " PcrData " folder and copy- paste it to the path where the user needs to store the backup data;

- **Data Recovery**: Locate the "PcrData" folder in the backup data location and copy-paste it back into the "PcrData" folder within the Galaxy Pro system software installation package.

5.5.3 Information Security

- Galaxy Pro system software uses user names and passwords to authenticate users and supports different levels of user permissions to access the system (see 5.4.5.5).

- Galaxy Pro instrument has data encryption and uses sophisticated MD5 anti-tampering algorithm protection, double transmission verification, private protocols, low memory reminders and other multiple protections to ensure the security of the network environment and the integrity of stored data. Users can close accounts, communication ports, shared files, services, etc. that are not intended for medical purposes, and take physical, technical and administrative measures to ensure the integrity and confidentiality of patient health data. Users can install anti-virus software, network maintenance software, and security software to achieve a safe and stable network environment; in addition, the LIS private network can also set up intranet boundary protection, application detection protection, and virtual private networks to ensure network security;

- Galaxy Pro system software has user operation logs. The log records the user's login, logout, opening ,closing, reset, running,stopping, exiting, data management actions, program management actions, user management actions, ,and the names of reagent programs executed by users along with their completion status.

5.5.4 Maintainability

- Galaxy Pro system software has operation logs. The log records the user's login, logout, opening ,closing, reset, running, stopping, exiting, data management actions, program management actions, user management actions,and the names of reagent programs executed by users along with their completion status.These logs facilitate identification and maintenance by after-sales personnel. Galaxy Pro system software cannot be modified by the user.

- External software environments and security software updates for Galaxy Pro instruments must meet the requirements specified in sections "4.2.6 Computer Requirements" and "5.5.1 Compatibility."

6 Operating Introductions

6.1 Overview

This section describes how to use the Automated Fully Enclosed qPCR Instrument for in vitro diagnosis (IVD) detection and manage the result data.

For details of perform the full process, please refer to Chapter 6.9.1;

For details of perform the extraction only, please refer to Chapter 6.9.2;

For details of perform PCR only, please refer to chapters 6.9.3 and 6.9.4.

6.2 Section Guide

The following table introduces the basic operations of the full process (extraction + PCR) when using this system :

Steps	Procedure	Section
1	Switch on the instrument	Section 6.3
2	Start system software	Section 6.4
3	Software login	Section 6.5
4	Open the compartment door	Section 6.6
5	Loading the iCassette	Section 6.7
6	Close the compartment door	Section 6.8
7	Run program	Section 6.9
8	Instrument runs automatically	Section 6.10
9	Instrument operation ends	Section 6.11
10	View results	Section 6.12
11	Operations ended	Section 6.13
12	Switch off the instrument	Section 6.14

Table 6-1 Standard workflow of the Galaxy Pro

6.3 Switch On The Instrument

The main power switch of the Galaxy Pro instrument is located at the power connector on the rear of the instrument. After pressing the main power switch, the instrument will be powered on but not turned on.

The power-on button is located directly in front of the Galaxy Pro. Press the button, the green light will turn on, and the instrument will turn on.

Press the button again, the green light goes out and the instrument shuts down.

6.4 Start System Software

Start the Galaxy Pro system software on the PC and double-click it.

6.5 Software Login

After opening the system software, the login interface will as shown in figure 6-1.

- Users who are not logging in for the first time directly fill in the user's account name and password and click "Login".

- Users who are logging for the first time, log in with the administrator account. Administrator account: Username: Admin, initial password: 123456, click "Login".

After successfully logging in to the software, the instrument will automatically perform self-checking as follows:

- Initialization, the position of each mechanical structure in the instrument is restored to the initial position, and the software pop-up window prompts initialization information;

- Fully automatic self-test, perform functional self-test on each functional component of the instrument, and software pop-up window prompts self-test information.

After the self-checking is completed, if there is no abnormality, the instrument displays the main interface as shown in figure 6-2,the instrument can be used normally.

Figure 6-1 Login Interface

Figure 6-2 Initial Interface

- 1: lease refer to Chapter 5.4.5.6 for How to change the user password.
- 2: Galaxy Pro consists of 2 modules, each module controls a tray independently (A single tray can hold 6 test kits), and each module can run independently in the control system.

> ⚠️ **Warning**: During the self-checking process, the instrument compartment door will automatically open and then close. This process is a normal self-checking process. Please do not touch the tray with your hands or forcefully pull the tray out. Otherwise, it may cause the hands pinching or damage the instrument.

6.6 Open The Compartment Door

- Clicks the "Open/Close " button on the main interface to open the instrument compartment door.
- If the tray is inside the instrument, remove the empty tray.

Figure 6-3 Galaxy Pro compartment door opening

6.7 Loading The iCassette

⑴　Click the "Run" button of the corresponding module of the system software, and the instrument compartment door of the instrument will automatically open, and the following SID input interface will as shown in figure 6-4

Enter sample information as follows:

- The corresponding positions of the reagent kit on the tray are 1 to 6 from left to right;

- Click the SID input box and enter the sample ID information corresponding to the reagent kit. You can use a barcode scanner to scan the sample barcode in sequence or manually enter the sample ID information ;

- Click the "..." PID input box, and enter the basic information of the sample corresponding to the reagent kit. The basic information of the sample is customized by the user.
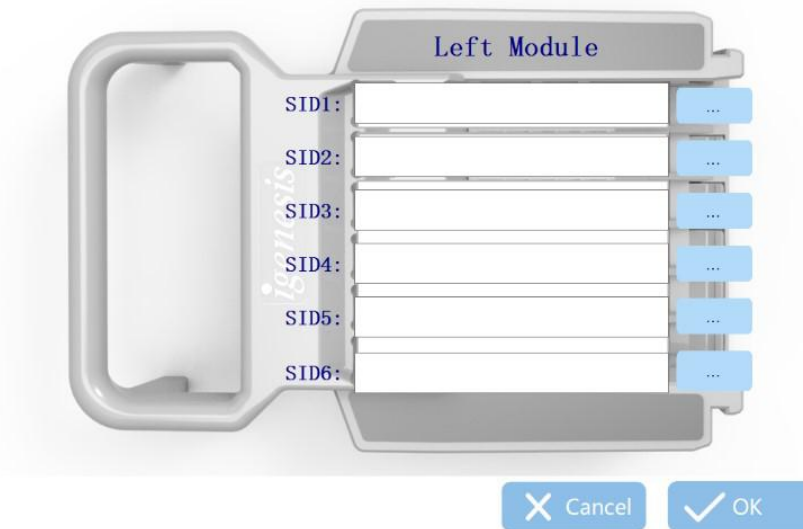

Figure 6-4 SID entry interface

⚠️ **Warning**:

- For the detection channel where the kit is placed, the corresponding SID and PID information must be entered, otherwise the subsequent detection program cannot be run.

- The user must enter the sample ID or name here, and there is no way to re-enter it in subsequent operations

⑵ Load the reagent kits with sample IDs entered into the iCassette tray in turn. After confirming that all reagent kits that need to be processed are loaded, load the iCassette tray into the instrument compartment.

Load the reagent kit as follows:

- Please take out the reagent kit that is stored in the proper ambient.

- Insert the reagent kit into iCassette Tray from the bottom and confirm that it is loaded in tray tightly. The channel position where the reagent kit is loaded into the tray must correspond to the SID channel where the sample ID is entered .

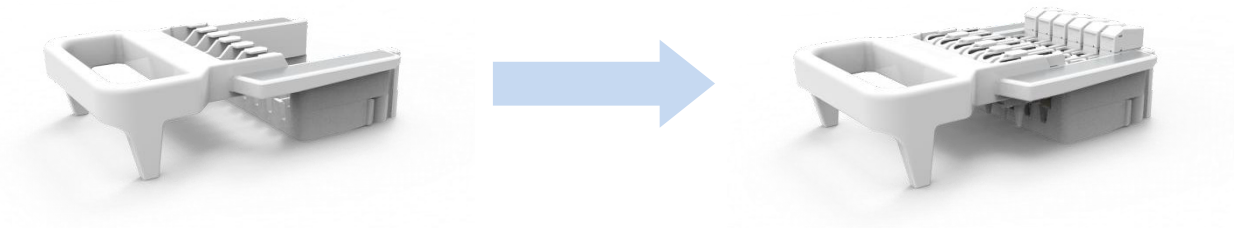● Confirm that the reagent kit does not shake or fall off after being inserted into the iCassette tray.

Figure 6-5 iCassette Tray loading

6.8 Close The Compartment Door

After confirming that the iCassette Tray loading is complete, click the "OK" button in the "Figure 6-4 Sample ID Entry" interface and the instrument will automatically start and scanning the code. At this time, the compartment door on the Galaxy Pro instrument automatically closes.

Warning: When opening and closing the compartment door, avoid touching the tray to prevent the risk of getting hands pinching.

6.9 Run Program

After completing the entry of sample information, follow the steps below to start running:

● Click the "OK" button in the "Figure 6-4 Sample ID Entry" interface, the tray will be automatically put into the compartment.

● The instrument automatically scans and reads the QR code on the kit;

● The system software will pop up a interface as shown in figure 6-6 based on the read information to remind the user to confirm the program that needs to be run, such as "Is device 1 sure to execute the program Test?" ;

● After clicking "Yes" to run the program, the instrument starts to run the experimental program;

● If the user selects the "No" button, it will immediately return to the main interface and the instrument will stop operation.
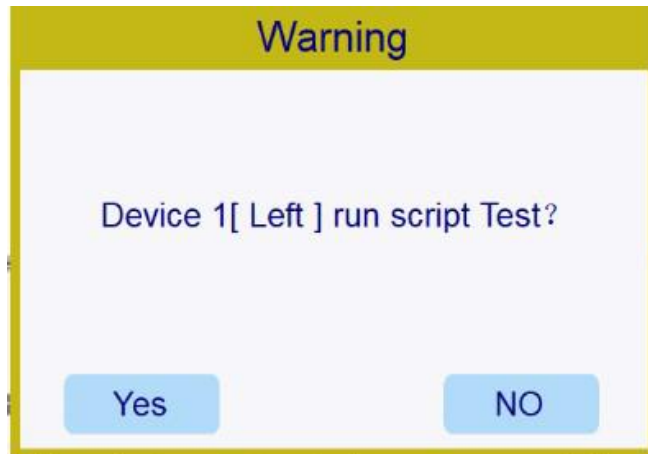

Figure 6-6 Run Confirmation

6.9.1 Automatic Whole Process

If the user needs to implement the whole process of automation, after scanning, the window will prompt that "Device 1 run script? XXXX?". XXXX stands for the program name, as shown in figure 6-6 (The sample drawing is only an example while the specific program name refers to the actual running program.). Click "Yes" to start the whole process of automation and "No" to stop the operation.

6.9.2 Nucleic Acid Extraction Function

- If the user needs to perform nucleic acid extraction, after scanning, the pop-up interface will remind the user to select "Extraction" and "PCR" function.

- The user clicks the " Extraction" button to start the nucleic acid extraction process and "Cancel" to stop the operation.

- If the user only uses it for extraction, after the nucleic acid extraction run is completed, the compartment door opens and the extraction ends.

- After exiting the compartment, take out the kit from the tray and collect the extracted nucleic acids in the tip of the elution chamber of the kit. The user can unscrew the tip counterclockwise (be careful not to press the top of the tip) and transfer the nucleic acid in the tip for subsequent experiments use. For the extarction kit operation procedure, please refer to the extraction kit instruction manual.
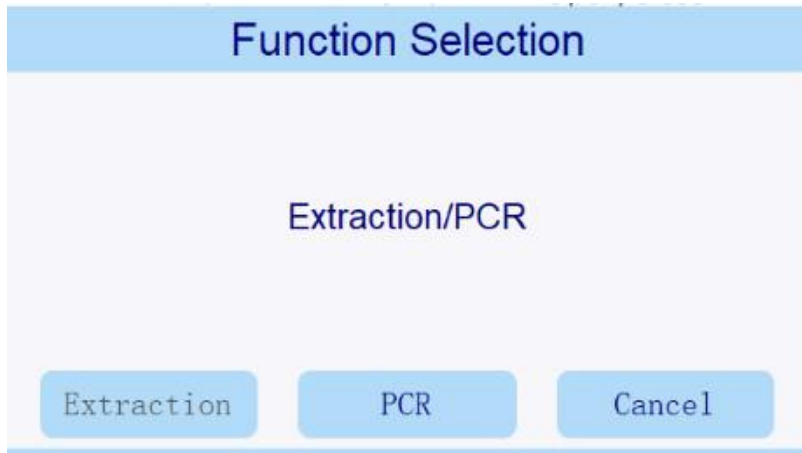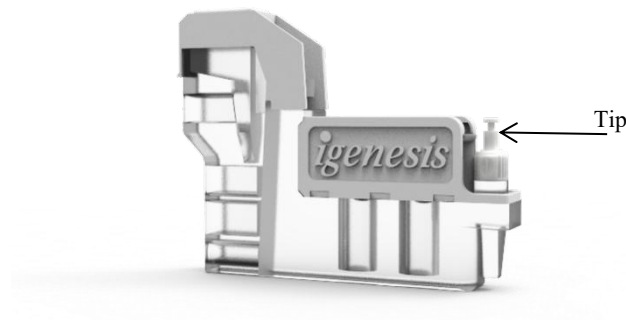
Figure 6-7 Function Select

Figure 6-8 Tip of the elution chamber

6.9.3 PCR Function

- Before the Galaxy Pro instrument starts to run the PCR process, the user needs to edit and save the PCR program according to the experimental requirements. Please see Section "5.4.5.13 PCR setting" for PCR programming.

- The user prepares the PCR reagent kit and PCR kit tube, replaces the empty PCR tube in the PCR reagent kit with PCR kit tube, and ensure the PCR kit tube is tightened to the qPCR consumable rack as shown in figure 6-9. Then load qPCR consumables into the iCassette tray.

- If the user needs to run the PCR process, after scanning, the pop-up interface will remind the user to select "Extraction" and "PCR", as shown in figure 6-7.
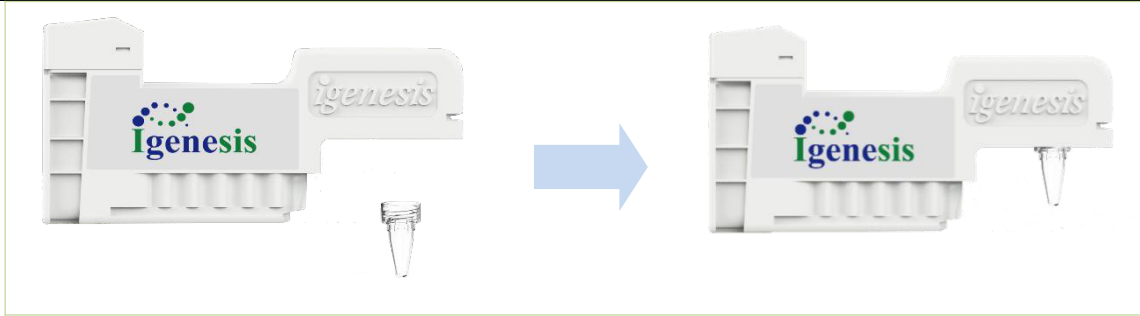
Figure 6-9 Load PCR Tube

- The user clicks the "PCR" button and select the PCR program to be executed, as shown in figure 6-10, and then click "OK" to start the specified PCR process while click "Cancel" to stop the operation.
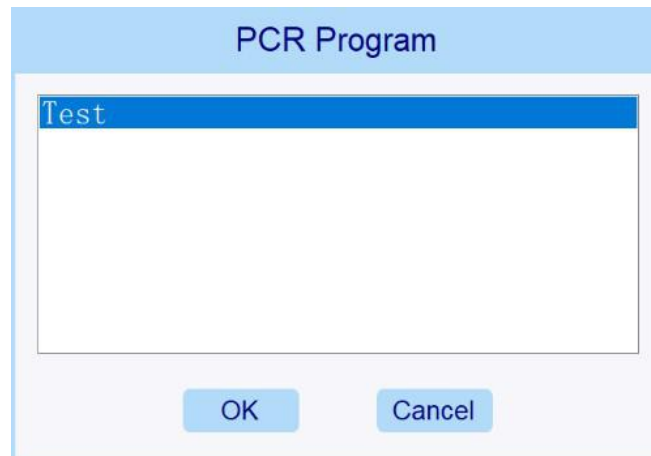

Figure 6-10 PCR program selection interface

- After nucleic acid extraction completed and obtaining nucleic acid in "Chapter 6.9.2 Nucleic Acid Extraction", user can adjust the amount of nucleic acid and add PCR reagent according to the PCR reaction demand.
- Execute chapters 6.7 to 6.9 again (load the kit-->put the tray into the instrument-->enter the sample ID information-->confirm the run);
- After the automatic code scanning is successful, the user selects the "PCR" button;
- Select the PCR program to be executed , start the PCR process, and complete the PCR operation.

6.9.4 Integrated PCR Reagent Testing

Galaxy Pro instrument combined with Galaxy EXT kit can use third-party PCR reagents . The operation steps are as follows:

- If the user needs to automate the entire process when using third-party PCR reagents , the user needs to

manually unscrew the PCR tube of the Galaxy EXT kit ;

- Fill the PCR tube with PCR reagent and screw on the cassette tightly;

- Load the Galaxy EXT cassette into the iCassette Tray ;

- Execute chapters 6.7 to 6.9 (load the kit-->put the tray into the instrument-->enter the sample ID information-->confirm the run);

- After scanning is successful, a pop-up interface prompts "Device 1 is sure to execute program XXX?", where XXX represents the program name;

- Click " Yes " to start the fully process ;

- Click "No" to stop the run.

6.10 Instrument Runs Automatically

When the instrument is running automatically, it will display the name, progress, remaining time, kit running position and other information of the current running program. Users can obtain the running status of the current experimental program through the kit dynamic diagram and arrange the time reasonably.
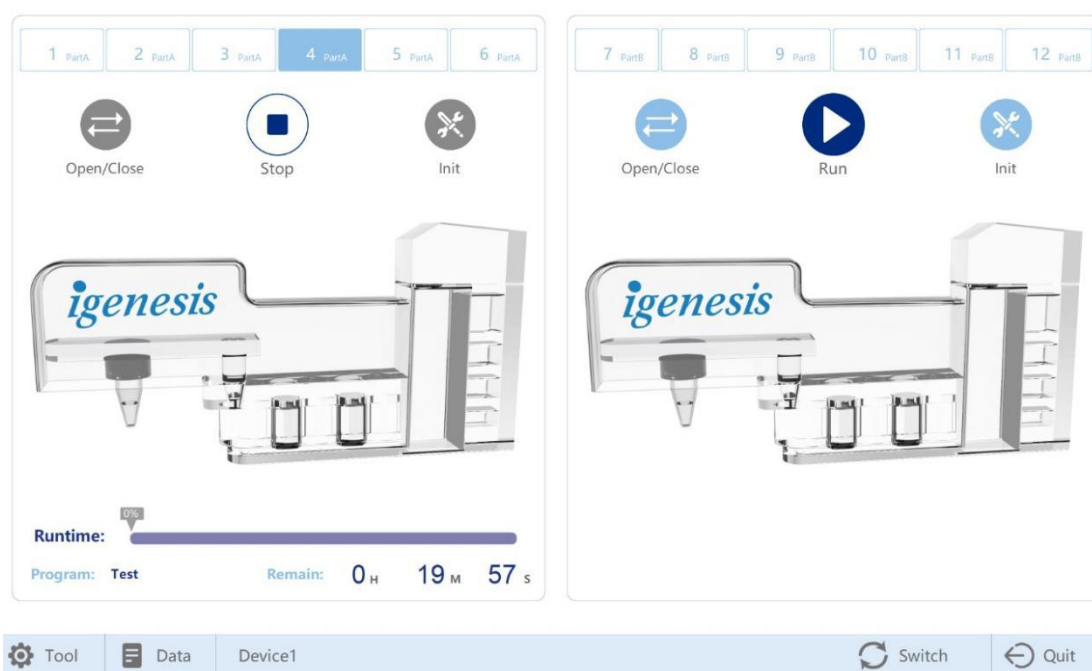

Figure 6-11 Program running interface

6.11 Instrument Operation Ends

- When the program is completed, the compartment door automatically opens and the run ends.

- After the program is executed, software switch to the result interface as shown in figure 6-12 . At the same time, the instrument performs initialization.

6.12 View results

When the program is completed, the Galaxy Pro software will display the final PCR amplification curve, melting curve and other information .

Figure 6-12 Results interface - amplification curve/melting curve

Figure 6-13Results interface

- **Print**: A printer can be connected to print reports;

- **Export**: Current data export button, which can export data in .xlsx or .PDF format

- **History**: Click to display the history results interface. After double-clicking a historical result, the user can choose to open the historical test record.

- **Save**: The sample type, patient ID, and threshold information after changes to the current results can be saved;

- **Sample type**: The sample type can be selected according to the actual situation;

- **Patient ID**: You can enter the patient information corresponding to the cassette.

- **Fluorescence Channel:** All fluorescence channels of the currently selected sample are Fam, Hex, Tamra, Rox/Texas Red, Cy5, Cy5.5 and Amca, and users can freely choose to view the amplification results of any fluorescence channel.

- **Threshold**: Fluorescence threshold is a fluorescence intensity standard set during the exponential growth period of fluorescence amplification curve. Double-click on the fluorescence threshold to be set to change the fluorescence threshold.

- **CT value**: Ct value, the number of amplification cycles when the amplification product reaches the threshold during PCR amplification.

- **Target**: target gene or fragment;

- **Melting threshold**: Set the fluorescence intensity standard for the melting curve;

- **Melting temperature (℃)**: the temperature at which half of the total DNA double helix structure is degraded;

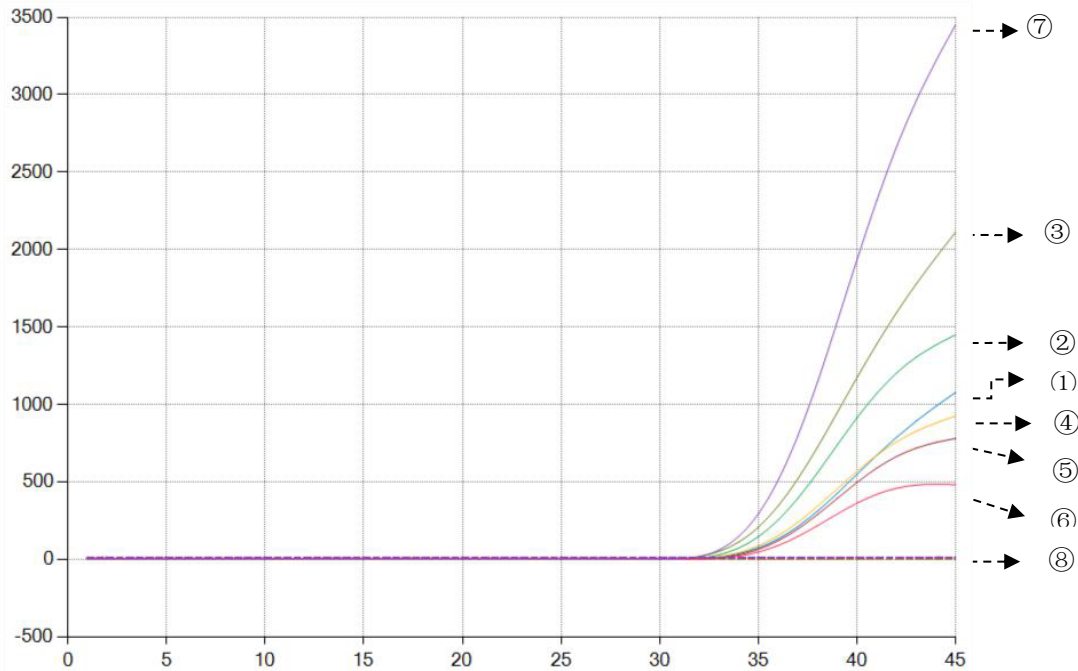- **Increment**: The fluorescence signal value after PCR amplification.

Figure 6-14 results interface-amplification curve

① Amplification curve: Amplification curve of FAM channel;

② Amplification curve: Amplification curve of HEX channel;

③ Amplification curve: Amplification curve of TAMRA channel;

④ Amplification curve: Amplification curve of ROX channel;

⑤ Amplification curve: Amplification curve of CY5 channel;

⑥ Amplification curve: Amplification curve of CY5.5 channel;

⑦ Amplification curve: Amplification curve of AMCA channel;

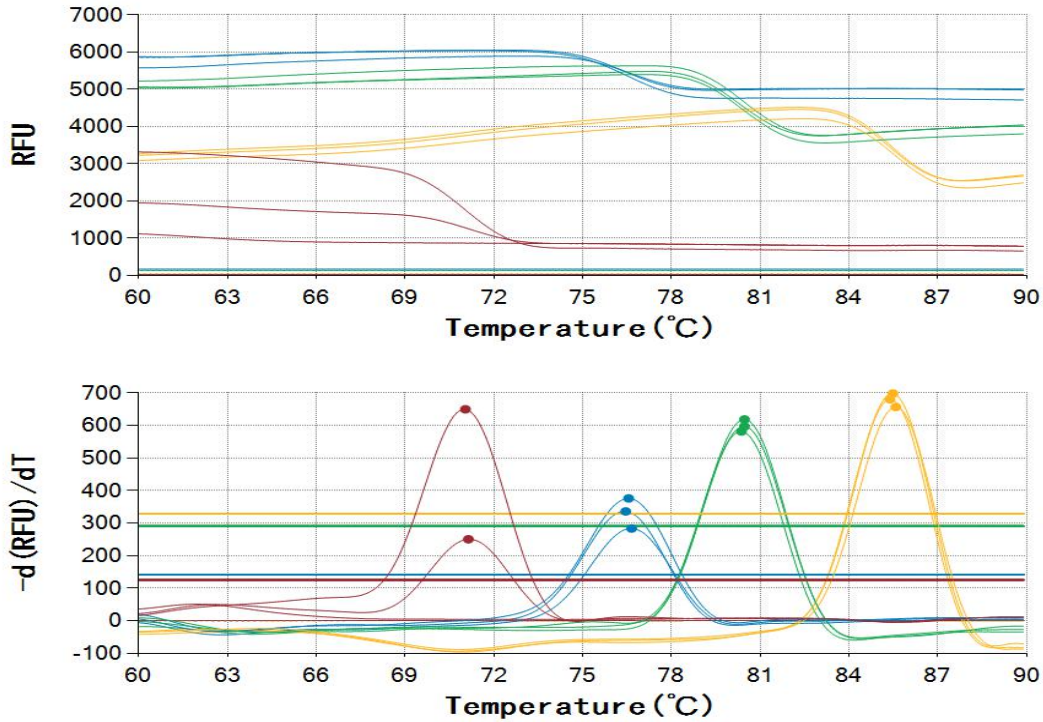⑧ Fluorescence threshold : xxx Threshold (shown as the dotted line in the figure above).

Figure 6-15 Result interface-melting curve

6.13 Operations Ended

The instrument will conduct the compartment-out automatically after the program is completed. User could take out the iCassette Tray from the iCassette Tray Holder, check the reagent kit appearance and then take out the reagent kit from iCassette Tray and discard the used kits into the medical waste bin.

> ⚠ **Warning**:
> - Only professionally trained personnel can handle used kits.
> - When handling toxic, corrosive, or infectious substances, it is essential to adhere to local safety regulations. Used disposable test kits should be discarded in medical waste bins and not thrown into public garbage systems. In case of accidental splashes or leaks, promptly disinfect with an appropriate disinfectant to prevent contamination of laboratory personnel and instruments

Then the user can start a new round of testing according to the method in 6.6 , or click the "Open/Close " button to close the compartment door and prepare to shut down the instrument.

Regarding the mishandling of equipment resulting in malfunction, follow these steps:

（1）Power Off: Immediately turn off the power to the instrument.

（2）Emergency Stop: Take urgent action to halt any ongoing processes.

（3）Contact Customer Service: Get in touch with customer service to report the issue and seek assistance.

6.14 Turn Off The Instrument

6.14.1 Power Off The Instrument

After processing, the user should turn off the instrument if it is no longer in use. Proceed as follows:

（1）Press the power-on button on the front of the instrument. After the green indicator light goes out, the Galaxy Pro instrument turns off;

（2）Press the main power switch on the rear of the instrument to power off the Galaxy Pro.

> ⚠️ **Warning**:
> - The Galaxy Pro instrument will enter a power standby mode if it is turned off without also switching off the main power switch. The power standby module will continue to consume power during this mode.
> - Before shutting down the instrument, ensure that no consumables are loaded in the tray. Otherwise, during the next boot self-testing, it may cause damage to the instrument.

6.14.2 Unplug The Power Supply

After confirm the Galaxy Pro instrument is powered off, the user needs to unplug the power cord.

7 Calibration and Quality Control

7.1 Overview

This section describes the calibration procedure for the Galaxy Pro instrument.

7.2 Calibration

The user does not need to calibrate the Galaxy Pro instrument. Igenesis has performed all necessary calibrations before the user receives the Galaxy Pro instrument. If user needs to arrange calibration, please contact the after-sale service.

7.3 Internal Quality Control

The accuracy of the test results can be ensured only when the instrument performs the test accurately. The Galaxy Pro instrument automatically controls the quality of each sample. In each test, the system will use one or more of the following measures for control:

- **Sample Processing Control**: Make sure the samples are processed correctly. The quality control material is included in the reagent kit, processed with the sample and detected by PCR.

- **PCR Detection control**: The instrument could verify the performance of PCR reagents and prevent false negative results. The internal standard is to evaluate whether there are possible inhibitors in the samples to be tested during PCR test. The internal standard should be positive in negative samples.

- **Probe Test**: the Galaxy Pro instrument adds the probe test function that is able to verify the labeled probe in the first stage during PCR detection. If the probe passes the inspection, it means that the probe inspection results meet the requirements.

7.4 External Quality Control

External quality control can be controlled according to the relevant reference standards or certification issued by local or national organizations to ensure the accuracy of instrument detection results.

8 Precautions

8.1 Overview

In this section introduces the instrument operation precautions.

8.2 Safety Precautions

Igenesis strongly recommends user to take the following precautions:

- Please take care with the detection result and data in the instrument.
- User shall protect patients' personal privacy and take measures from physical, technical and administrative aspects to ensure the integrity, confidentiality, authenticity and reliability of patients' personal health data, such as network and system access control, user identity authentication, installing anti-virus software, etc. in order to meet the relevant standards of network security.
- In particular, the system administrator should be configured for all system users, and the system administrator has the highest authority. Besides, the users shall not access to each other's data.
- Consult your system administrator if it is necessary so as to ensure that all applicable regulations are followed internally.

8.3 Application Environment Requirements

Before installing the Galaxy Pro instrument, please make sure your laboratory meets the space and environmental requirements specified in Section "4.2 Installation Requirement".

8.4 Instrument and Software

Please follow the tips below. When the test is in progress:

- Please do not move the instrument.
- Please do not run other software in the computer.
- Please do not change the date and time of the computer.
- Please do not set the computer as auto-shutdown or dormancy mode.

8.5 Detection

For each detection, please be sure to follow the requirements of the user manual of the instrument.

8.6 Reagent Kit

In order to protect against the hazards from cross-contamination, please do not reuse the reagent kit.

⚠️ **Warning**: Please dispose the elution after each experiment in light of the laws, regulations and lab rules to protect the lab from contamination.

⚠️ **Warning**: The used reagent kit shall be disposed as medical waste and do not dispose it into the public trash site.

8.7 iCassette Tray

If damage or abrasion occurs on the iCassette Tray, please immediately contact Igenesis after-sale service or the agent. It is recommended to replace the iCassette Tray every two years or each 4000-time test run.

9 Service and Maintenance

9.1 Overview

This section introduces how to maintain the Galaxy Pro instrument.

9.2 Maintenance Task

Although the system itself has the function of preventing cross-contamination and ensuring accurate results, as a preventive measure, user should regularly check and clean the instrument. The table below lists the basic maintenance tasks user can perform.

Task	Section
Instrument Disinfection	Section 9.3
Instrument Cleaning	Section 9.4
iCassette Tray Holder Cleaning	Section 9.5
iCassette Tray Cleaning	Section 9.6
Others	Section 9.7

9.3 Instrument Disinfection

In order to prevent bio-hazards, user should disinfect instrument surface regularly.

⚠️ **Warning**: Please turn off and unplug the instrument before disinfecting the instrument.

⚠️ **Warning**: Galaxy Pro instrument must be disinfected before cleaning.

⚠️ **Warning**: If the hazardous substance leaks to instrument surface or interior, please disinfect in a proper way.

⚠️ **Warning:** Please do not use the detergent or disinfectant that may be reacted with the instrument materials.

⚠ **Warning:** If user is not sure about the compatibility of the detergent or disinfectant to the instrument materials, please contact the after-sale service.

⚠ **Warning**: If hazardous substances leak to the surface of the iCassette Tray of the Galaxy Pro instrument or enter the interior of the instrument, the following disinfection methods should be adopted.

- When the Galaxy Pro instrument is powered on and idle, click on "Open/Close " on the system interface.

- The "compartment door" is opened, load the iCassette Tray (No reagent loaded) to the tray holder with 1/3 part inside, as shown in figure 9-1.

- In this case, the Galaxy Pro instrument should be shut down and unplugged.

- Turn on the UV disinfection lamp or UV disinfector to irradiate the Galaxy Pro instrument compartment door, the iCassette Tray Holder and iCassette Tray area.

- After the UV irradiation lasts for 30 minutes, the disinfection of the Galaxy Pro instrument is finished and turn off the UV disinfection lamp.
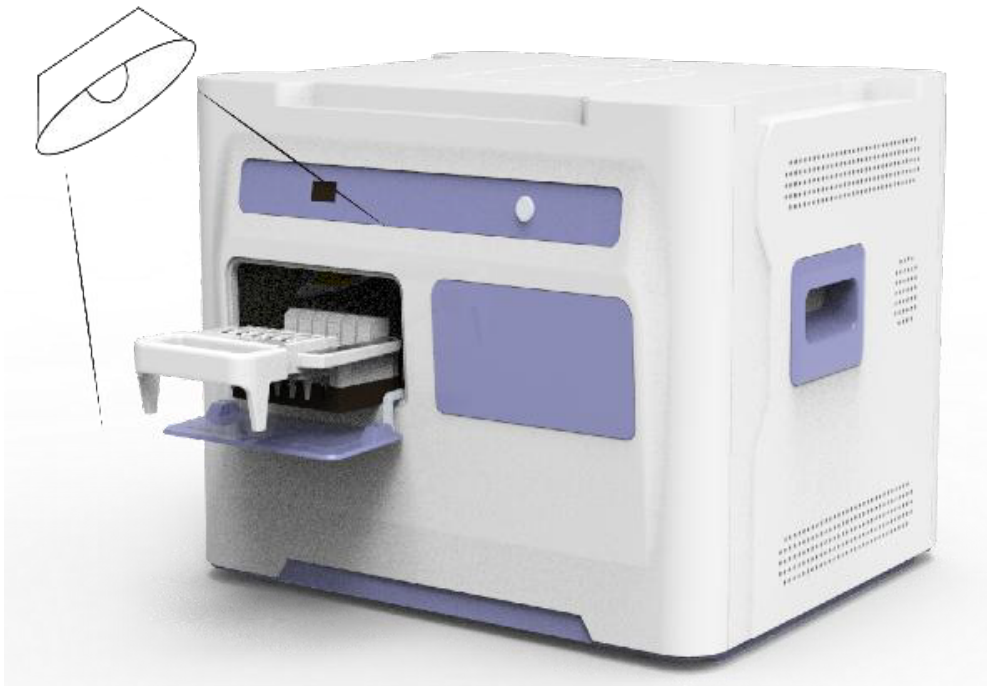
Figure 9-1 UV Disinfection

9.4 Instrument Cleaning

It is recommended that you clean the surface of the instrument once a month or more frequently if necessary. To do this, you need the following materials:

● 75% ethanol;

● Lint free cloth;

● Disposable gloves;

Please make sure you wear disposable gloves during cleaning, which can protect you from direct contact with bio-hazards.

Please clean the surface of the instrument as follows:

a. When you use or spray cleaning solution on the instrument, please keep cleaning solution away from the AC power module.

b. Wipe the surface of the instrument thoroughly with a lint free cloth;

c. Use the lint free cloth wet by 75% ethanol to wipe the surface of the instrument again.

d. Discarded lint free rags should be disposed according to standard laboratory procedures.

⚠ **Warning**: Before the cleaning,the Galaxy Pro instrument should be shut down and unplugged.

⚠ **Warning**: Do not pour liquids inside the instrument.

⚠ **Warning**:Users should not use cleaning solutions containing sodium hypochlorite, caustic soda, sulfuric acid, sodium hydroxide, hydrochloric acid, or other strong acid or alkali components to clean the Galaxy Pro instrument. Additionally, enzymatic cleaning agents should not be used for cleaning the Galaxy Pro instrument. Avoid using cleaning or disinfecting solutions that may react dangerously with the components or materials inside the Galaxy Pro instrument. If there are any doubts about the compatibility of cleaning solutions with the Galaxy Pro instrument's components or materials, it is advisable to consult the manufacturer or authorized representatives.

9.5 iCassette Tray Holder Cleaning

It is recommended that you clean the iCassette Tray and iCassette Tray Holder once a month or more frequently if necessary. To do this, you need the following materials:

- 75% ethanol;
- Lint free cloth;
- Disposable gloves;

Please clean the iCassette Tray holder as follows:

a. Please wipe the iCassette Tray holder thoroughly with lint free cloth after opening the compartment door and turning off the instrument.

b. Wipe the iCassette Tray holder thoroughly with lint free cloth wet by 75% ethanol.

c. Turn on the instrument and close the compartment door.

d. Discarded lint free rags should be disposed according to standard laboratory procedures.

> ⚠️ **Warning**: If hazardous substances leak to the surface of the iCassette Tray of the Galaxy Pro instrument or enter the interior of the instrument, the following disinfection methods should be adopted.

9.6 iCassette Tray Cleaning

It is recommended that you clean the iCassette Tray often. To do this, you need the following materials:

- 75% ethanol;
- Lint free cloth;
- Disposable gloves;

Please clean the iCassette Tray as follows:

a. Please wipe the iCassette Tray thoroughly with lint free cloth wet by 75% ethanol.

b. After 5 minutes, please repeat Step a.

c. Discarded lint free rags should be disposed according to standard laboratory procedures.

9.7 Other Maintenance

If the fuse is broken during instrument running, please replace the fuse according to the Section "4.2.5 Fuse Requirement". In order to ensure the instrument power and the fuse in a good performance, please replace the fuse as follows:

a. Please take out the fuse tube with the proper tool in the power switch area at back of the instrument, as shown in figure 9-2.

⚠️ **Warning**: Please switch off and unplug the instrument before replacing the fuse.

Figure 9-2 Take Fuse Box

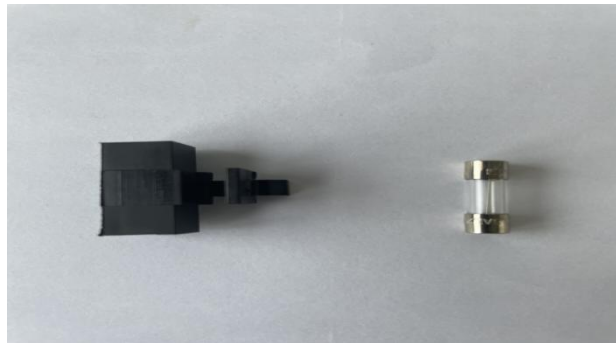**b.** Please take off the original fuse and replace it with a new one, as shown in figure 9-3.

Figure 9-3 Take Fuse Tube

c. Please load the fuse box with the new fuse tube inside to the slot, as shown in figure 9-4.

Figure 9-4 Take Fuse Tube

Within the instrument validity, Igenesis could provide the chargeable service to keep the instrument in a good condition. If the instrument runs out of the validity, Please do not dispose the instrument in a random way and shall contact Igenesis to get a better way to dispose it.

10 Troubleshooting

10.1 Overview

This section will provide the tips how to solve the problems or error messages that may occur on the instrument.

10.2 Fault Table

This table shows the possible problems that may occur on the instrument.

Fault	Reason	Solutions
Load the iCassette, click "Open/Close" to put them into the compartment, the iCassette is stuck and cannot enter the compartment normally;	1. iCassette loading error; 2. The instrument fails;	1. Reload iCassette correctly; 2. Please contact the after-sale service;
Click "Run" and the error "Reagent Kit Not Detected" is reported;	1. iCassette not loaded; 2. The instrument fails;	1. Loading iCassette; 2. Please contact the after-sale service;
Load the iCassette, click "Run", and an error "Cassette format error" is reported;	1. The QR code of iCassette is incorrect and cannot be recognized; 2. The instrument fails;	1. Replace the correct iCassette that can be recognized by the system; 2. Please contact the after-sale service;
Load the iCassette, click "Run", and an error "Device 1 have no script" is reported;	1. This system does not support the QR code of this iCassette;	1. Replace iCassette within the scope of support of this system;
Error "Device motor did not reach the specified position" is reported;	1. The position sensor is blocked by tiny foreign objects such as dust;	1. Please cut off the power and restart the instrument； 2. Please contact the

	2. The instrument fails;	after-sale service;
Error "Motor: X Error" is reported;	1. The position sensor is blocked by tiny foreign objects such as dust; 2. The instrument fails;	1. Please cut off the power and restart the instrument； 2. Please contact the after-sale service;
Error "PCR Heater error [X]" is reported;	1. The heating tip of the PCR module is faulty;	1. Please contact the after-sale service;
Error "Heater error (XX)" is reported;	1. The heating tip of the pyrolysis heating or elution heating module is faulty;	1. Please contact the after-sale service;