Igenesis

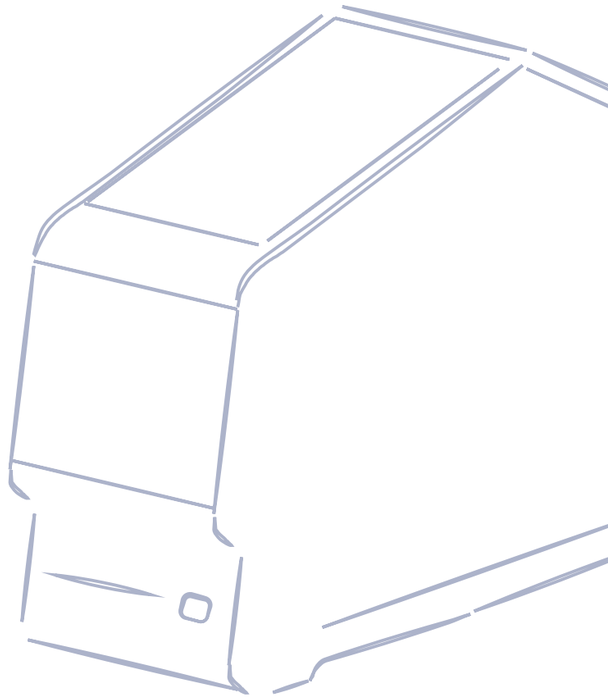
IGENESIS(SHANGHAI)CO, LTD.

Preparation Date：March 17,2025
Version：A/0
Name of Manufacturer：Igenesis (Shanghai) Co., Ltd.
Manufacturer Address：Floor 3, Building 1, Lane 500, Furonghua Road, Pudong New Area, Shanghai, P. R. China.

Galaxy Neo

Automated Fully Enclosed qPCR Instrument

Galaxy Neo User Manual



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Preface

Description

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

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 Neo

Product Specifications: Galaxy Neo has four models, including 1.0, 2.0, 3.0 and 4.0 which is classified by the configurations. Please see details in the following table:

Specification	Configuration
1.0	One Instrument
2.0	2-cascade Instrument
3.0	3-cascade Instrument
4.0	4-cascade Instrument

Intended Use: Galaxy Neo 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 Neo

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.**
	**Serial Number**
	**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**
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC

Contact Information

Igenesis (Shanghai) Co., Ltd.

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Intellectual property

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 Neo user manual which is attached with the instrument gives a detailed description of the use, function and operation of the Galaxy Neo 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 Neo 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 Neo instrument
3 Instrument Characteristics	The performance characteristics and parameter of Galaxy Neo

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

1.4 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.

- This instrument must be used with the dedicated power adapter provided by Igenesis.
- In connection of the power cord, ensure that the power supply is turned off.
- It is forbidden to touch the power switch and power cord with wet hands.
- It is forbidden to unplug and plug the power cord 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 Neo 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.

1.5 Label

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

Sign	Title	Description
O	Power off	Cut off instrument power supply.
|	Power on	Provide power for instrument.
	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 Neo 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 Neo may cause hands pinching.
	In Vitro Diagnostic	It indicates that Galaxy Neo is an In Vitro Diagnostic (IVD) device.

Please refer to the following labels position on Galaxy Neo.

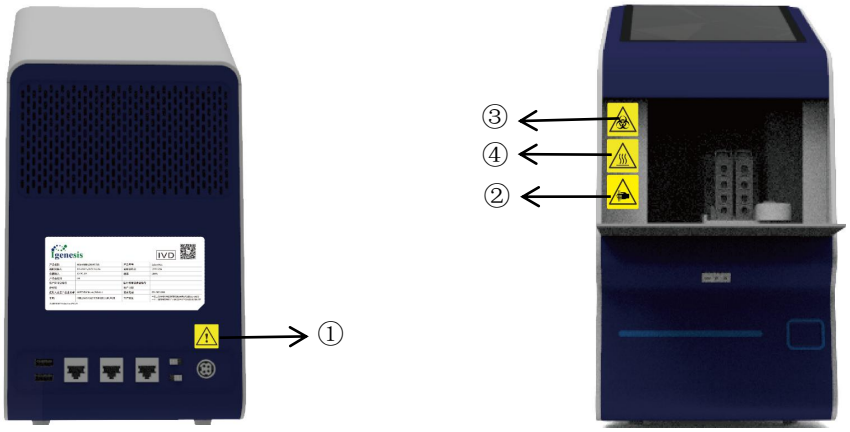


Figure 1-1 Label Position

① **Warning:** User shall not open instrument shell or replace other components.

Any damage to instrument will not covered under the warranty.

② **Warning Hands Pinching:** When opening or closing the sample chamber door, please do not reach out to touch the tray and sample chamber door as there is a risk of your hands being pinched

③ **Biohazard:** Safety masks and gloves must be worn to handle toxic, corrosive or infectious substances; if a spatter or leakage occurs accidentally, appropriate disinfectant should be used immediately to prevent contamination for laboratory personnel and instruments.

④ **High Temperature**: Do not touch this area to avoid burn.

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 Neo 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 Neo is clinically, intended to extract, purify and quantitatively detect the target nucleic acid (DNA/RNA) from human being samples, such as oropharyngeal swabs, nasopharyngeal swabs, genital tract swabs, sputum, stool, blood samples, cervical exfoliated cells, and others. The item of pathogen is one of them.

2.4 Structure and Components

Galaxy Neo mainly consists of ultrasonic module, extraction module, PCR module, power supply, system

software (release version 1.0, integrated in the host) and tray. The ultrasound module mainly consists of mechanical movement unit and electronic system. The extraction module consists of mechanical motion unit, temperature control unit and magnetic unit. The PCR module consists of optical components, temperature control unit, electronic system and related software.

The instrument structure is as shown in below figure:

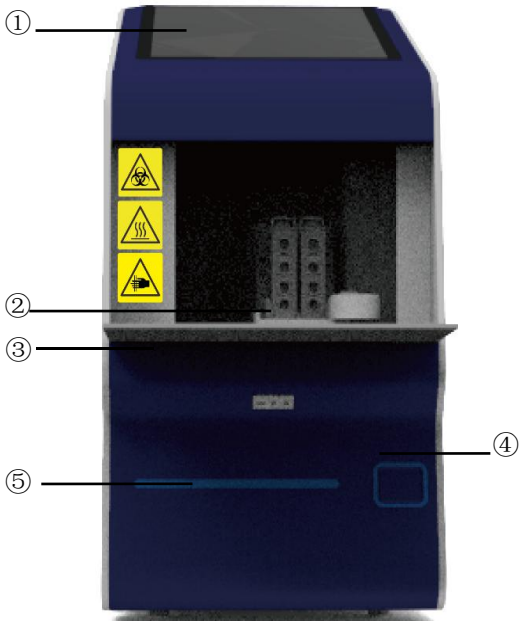


Figure 2-1 Front View

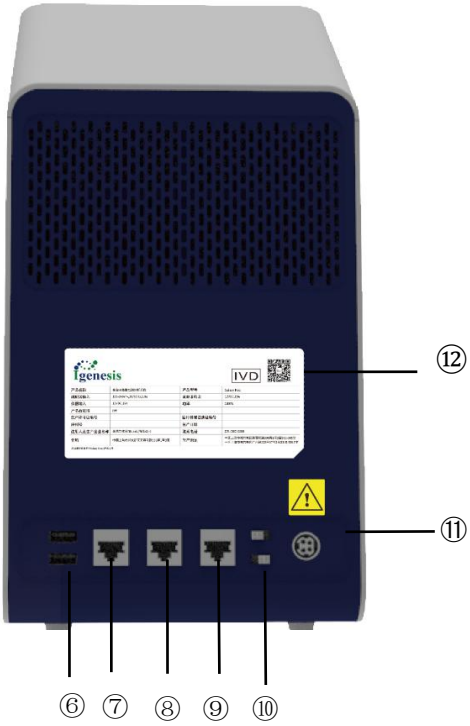


Figure 2-2 Rear View

1. Display screen	2. iCassette Tray Holder	3. Compartment Door	4. Switch
5. Power Indicator	6. USB 1、USB 2	7. LAN	8. CAN IN
9. CAN OUT	10. I/O(IN)、I/O(OUT)	11. Power Input	12.Nameplate

1. **Display screen**: Install, display and control Galaxy Neo system software
2. **iCassette Tray Holder**: This is used for placing the iCassette Tray.
3. **Compartment Door**: It can be opened and closed by software and shall be opened when load or unload iCassette Tray while shall be closed when the instrument is running.
4. **Switch**: The switch is located in instrument face. After plugging the power cord and turning on power switch,

please press the instrument switch over 1 second and the instrument will be started with the power indicator is blue. While, press the instrument switch over 5 seconds when the instrument is on to shut down the instrument. The power indicator will be off.

5. **Power Indicator**: It indicates the status of the instrument. The indicator is off when the instrument is shutdown while it is blue when the instrument is on. The monitoring procedure is blue breathing light. The indicator light flashes periodically in the event of a fault.
6. **USB 1, USB 2**: Two USB Type A ports for exporting results to storage devices such as USB flash drives.
7. **LAN:** RJ-45 wired network interface.
8. **CAN IN**: This is a dedicated port where shall use the matched cord from Igenesis to connect 4 instruments maximally and simultaneously.
9. **CAN OUT**: This is a dedicated port where shall use the matched cord from Igenesis to connect 4 instruments maximally and simultaneously.
10. **I/O(IN)、I/O(OUT)**: The DIP switch I/O (IN) corresponds to the CAN IN port, and the DIP switch I/O (OUT) corresponds to the CAN OUT port. To disable the port, move the switch to the left (OFF position); to enable the port, move the switch to the right (ON position).
11. **Power Input**: 100-240V～(input voltage: 12VDC) Power adapter interface of the instrument.
12. **Nameplate**: It displays the instrument model, SN, etc.

2.5 Accessories

iCassette Tray: It is used for loading reagent kit (iCassettes).

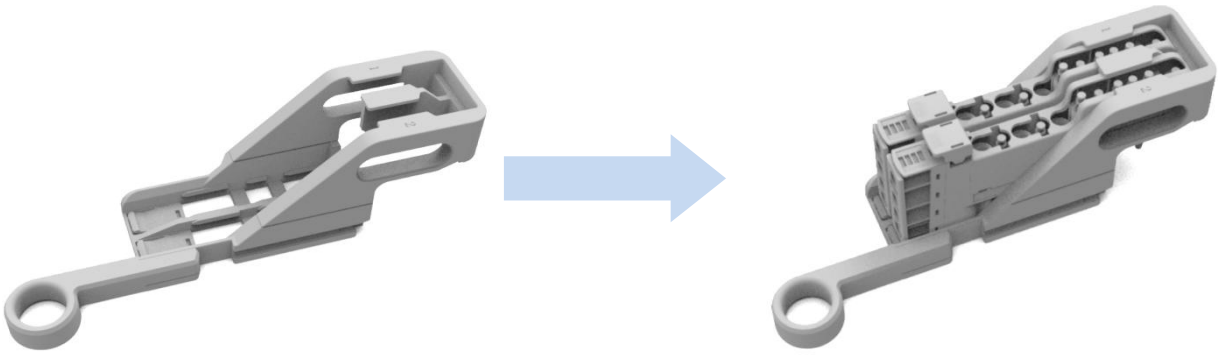


Figure 2-3 iCassette Tray

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

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

Power adapter: The power adapter is used to supply DC power to the instrument, Please use the power cord provided by Igenesis.

Communication Cord: It is recommended to use the communication cord by Igenesis.

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

2.6 Running Environment

- Hardware: 64-bite RK3588 Microprocessor;
- Software: Android 13 operating system and above;
- Network: The 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 Neo instrument characteristics and key parameters.

3.2 General Specifications

- **Instrument Specification:**

  Dimension: 448mm(L) × 178mm (W) × 331mm (H);

  Weight: 15.6 kg;

- **Application Environment:**

  Temperature: 15℃-35℃;

  Relative Humidity: 20%-80%RH;

- **USB Port:**

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

3.3 Throughput

The instrument owns 2 throughputs which can be expanded to 8 maximally via 4 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/ NED	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:**
  ≤0.2℃
- **Temperature Uniformity:**
  ≤1.0℃
- **Max. Heating Rate:**
  ＞15℃/s
- **Max. Cooling Rate:**
  ＞12℃/s
- **Melting temperature support range:**
  5℃～99℃
- **The resolution of melting temperature:**
  0.02℃

4 Instrument Installation

4.1 Overview

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

In order to ensure the proper operation of the instrument after installation, the installation and initial settings at delivery of Galaxy Neo 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 Neo 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 Neo instrument shall be placed on a stable and horizontal platform with a bearing capacity ≥20 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 210cm.

4.2.2 Electrical Requirements

- Power Voltage: 100-240VAC (Input voltage: 12VDC)；
- Overvoltage category: II；
- Power Frequency: 50/60Hz;
- Input power：≥200VA 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 Neo instrument must be connected to a three-pin grounded socket conforming to safety standards. The power cord should be three-core and matched with the instrument.

4.2.3 Electromagnetic Compatibility

The emission and disturbance immunity of Galaxy Neo instrument is in conformity with IEC61326-2-6.

- 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%～80%;
- 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.
- 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 Network Security Requirements

- Please exit the computer dormancy mode while the instrument is running.
- Please keep the display on while the instrument is running.
- Please install the professional antivirus software, data security defense software and network security protection software and regularly upgrade them.
- 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.

4.3 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 Neo User Manual	1
3	Quick Guide	1
4	Warranty Card	1
5	Certificate of Quality	1
6	Power Adapter	1
7	Power Cord	1
8	iCassette Tray	1
9	PCR Tube Installation Tool	1
10	System Software（USB Flash Drive）	1

11	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 Electrical Requirement”.
- If install more than one instruments, the power of the grid shall be greater than or equal to the total power of instrument’s.
- Please close the AC power switch, insert the power cord in the package into the jack and then plug the instrument.
- Please ensure that the DIP switches for the IN and OUT ports are set to the correct positions.

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 USB port of the instrument..
- Find and open the "Galaxy Neo.apk" software installation package in the USB flash drive, double-click "Galaxy Neo.apk" and follow the software installation prompts to complete the software installation. Igenesis will provide all services of the third-party ready-made software within Galaxy Neo system life cycle.
- After the installation is complete, please double-click the igenesis shortcut icon to open the Galaxy Neo system software. If the software fails to open, please contact the after-sale service.
- 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 "Power Switch" key of the Galaxy Neo instrument. When the "Power Switch" is on, the instrument is turned on.
- Press the "Switch" key for 1 second to turn on the instrument.

- Please double click the “Galaxy Neo” shortcut icon 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-inspection.
- 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

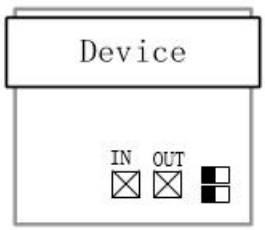
Please shut down the instrument by following the below steps.

- Log out the system software.
- Press instrument switch more than 3 seconds to shut it down.
- Please unplug the instrument if it is not used for a long time.

4.3.7 Instrument Cascade

The system supports the cascaded operation of up to 4 Galaxy Neo. The cascaded installation can be performed according to the following steps.

- Place the Galaxy Neo to be cascaded from left to right on the workbench according to the requirements for a single instrument.
- Connect the power cord of each instrument to the power grid according to the installation requirements for a single instrument. At the same time, check that the I/O (IN/OUT) DIP switches on the back of each instrument are on the left side (in the off state). as shown in Figure 4-1. If not, please switch them to the left.



IN :CAN IN port, × indicates that the port is not connected.

OUT :CAN OUT port, × indicates that the port is not connected.

:This symbol is the DIP switch. The upper part is the DIP switch I/O(IN) of the CAN IN port, and the lower part is the DIP switch I/O(OUT) of the CAN OUT port. The black squares represent switchs. They are turned off when they are set to the left and turned on when they are set to the right.

Figure 4-1 Illustration of Rear Ports and DIP Switches (Single Unit)

- Shift the I/O (OUT) DIP switch on the back of the first Galaxy Neo to the right (as shown for Instrument 1 in Figure 4-2, while the I/O (IN) DIP switch remains on the left). Then, insert the cascaded communication cable provided by Igenesis into the CAN OUT port of the first instrument, and connect the other end of the cascaded communication cable to the CAN IN port of the second instrument. At the same time, shift the I/O (IN) DIP switch of the second instrument to the right.If you need to continue the cascading, you can repeat the process of inserting the communication cable into the CAN IN/OUT ports of the instruments while shifting the I/O (IN/OUT) DIP switches to the right to open them. If the CAN IN/OUT ports do not need to be connected with the cascaded communication cable, the corresponding I/O (IN/OUT) DIP switches should be left in the closed state (on the left). Follow the above method to complete the physical connection of up to four instruments.

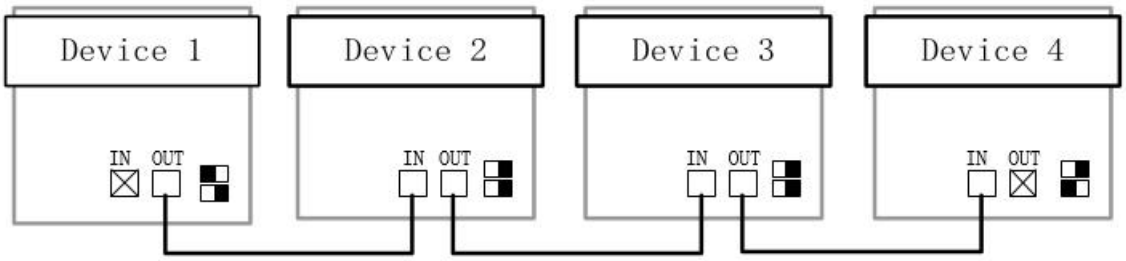


Figure 4-2 Cascade diagram of four units

- Open and log in the first unit 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 "Turn on all cascaded devices sequentially with intervals of at least 10 seconds between each operation, then click 'OK' after completion."and user could follow the software prompts to operate.
- After the instruments are connected, the first unit software 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 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%-80%, 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 , adapter and communication cord.
- 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.

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 the igenesis icon to open the “Galaxy Neo.apk” system software, 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

① **Instrument Connection Status**: When the instrument is correctly installed and communication is successfully established, it will be in an unlocked state. The numbers 01–04 indicate the instrument's number in the cascade configuration.

The description of the keys in the interface.

Key	Description

Uninstall means the instrument is uninstalled or cascaded improperly.

Available means the instrument is installed properly and connected to system software.

Unconnect means the instrument is disconnected.

Initializing means the instrument is connected properly and the motor is moving to the zero position.

Checking means the instrument is initialized and starts to self-checking.

Scanning means the instrument is performing scanning before running the program.

Running means the instrument is currently executing a program

Finished means the instrument program execution has been completed.

② **System Time**: It is the system time displayed in computer in real time.

③ **User Icon**: It is the username that logs in currently.

④ **Open/Close**: Open or close the compartment door.

⑤ **Results**: User could click this key to view the history results of the current user.

⑥ **Setting**: To check the instrument's information, Test Script Management, etc.

⑦ **Exit**: User could exit and close the software by clicking this key.

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.

5.4.2 Results

After clicking **Results**, it enters the results checking interface, as shown in figure 5-3.

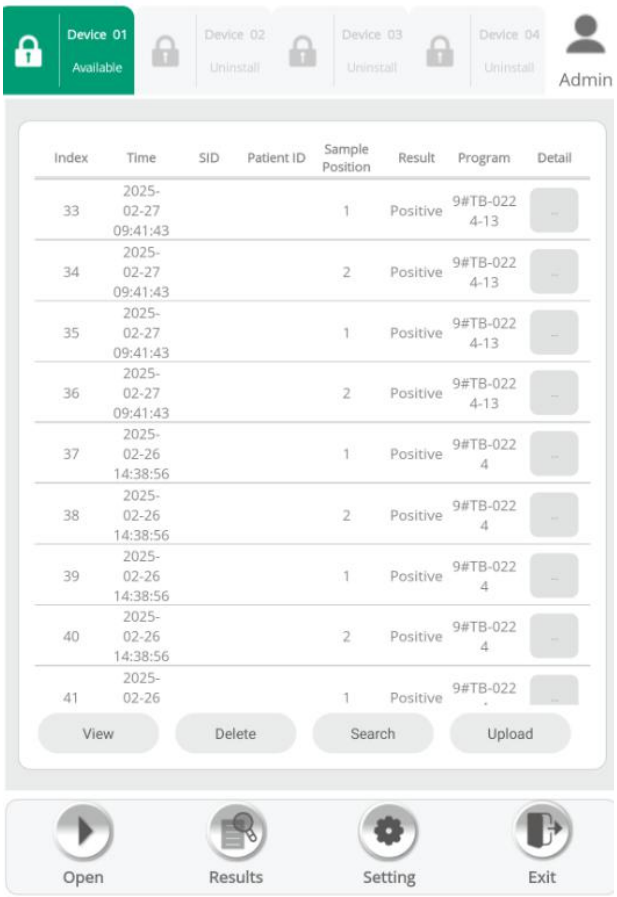


Figure 5-3 Results Interface

- The results interface consists of **index**, **time**, **SID**, **patient ID**, **sample type**, **sample position**, **iCassette Code**, **result**, **upload state**, **upload time**, **program**, **user**, **instrument**, etc.
- Four function keys are at the bottom of this interface, including **View**, **Delete**, **Search** and **Upload**.
- The data information excludes the user's real information which is only the character code.

- Click the result to select it while clicks it again to cancel the selection. Maximally, 2 results can be selected.
- After selecting the result, the 4 function keys at the bottom can be used, or the system software will prompt "Please select the sample first."
- Click **Search** and there pops up a window where user could filter the experiment results by selecting **SID**, **program**, **device**, **user**, **start date** and **end date**.

5.4.2.1 Result View

User could select one or more than one result records and click View, the result view interface is as shown in figure 5-4.

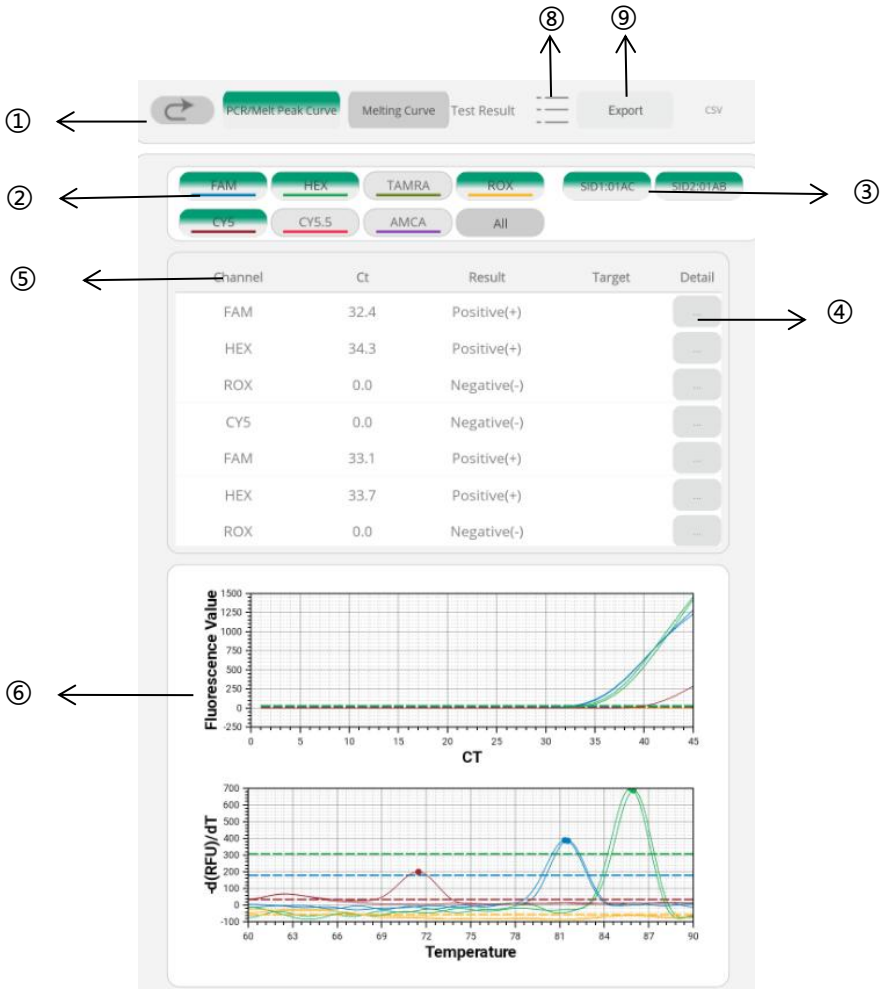


Figure 5-4 Results interface - amplification/Melt Peak curve

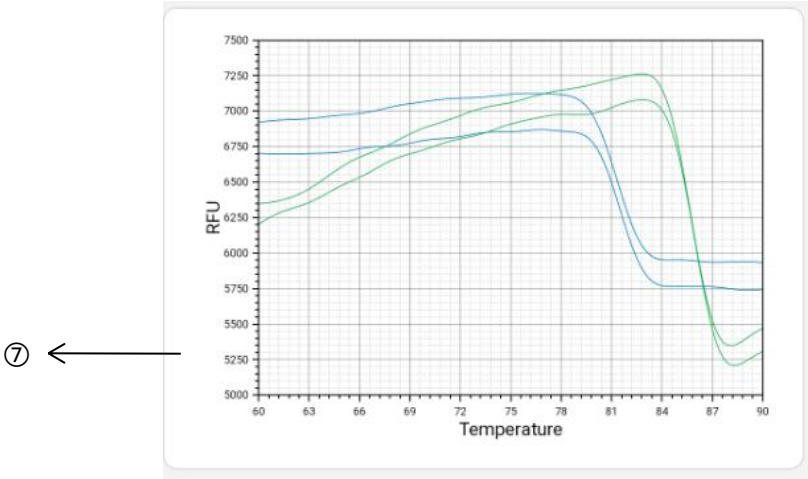


Figure 5-5 Results interface - melting curve

① **Back：** Click this key to return to last step;

② **Fluorescence Channel**: Click to select the channel and click again to cancel the selection. The selected fluorescence will be displayed in the result curve;

③ **Select Sample**: Click to select the channel and click again to cancel the selection. The sample result table will display the selected sample's name, fluorescence channel, threshold value, Ct value;

④ **Details**: Data details of the currently selected fluorescence channel;

⑤ **Sample Table**: It is the result table of the current selected sample and fluorescence channel;

⑥ **Amplification /Melt Peak Curve**: It is the Amplification /Melt Peak Curve of the current selected sample and fluorescence channel;

⑦ **Melting Curve**: It is the melting curve of the current selected sample and fluorescence channel;

⑧ **Sample Edit**: The sample ID, patient ID, sample type and other information can be modified according to the actual situation; **Print**: A printer can be connected to print reports;

⑨ **Export**: The current data export button can export data to CSV, TXT, XSLX, PDF format;

The user could select one or more than one result records and click **View**, then click **Export**, the result export interface is as shown in figure 5-6. The user could define a file name and the save as type could be CSV, TXT, XSLX, PDF. Here only exports the current selected result record.

5.4.2.2 Result Deletion

User could select one or more than one result records and click Delete. The pop-up window will prompt "Are you sure to delete the result record?". Click "Yes" to delete it while "No" to keep it. If the result record once

deleted, it will never be recovered.

Warning: Please double check the result record to be deleted because it cannot be recovered. Igenesis recommends that user should backup the experiment data.

5.4.2.3 Result Search

Click **Search** to filter and check the experiment result, as shown in figure 5-6. The experimental result data can be filtered according to "SID", "Program", "Device", "User", "Start Time" and "End Time".

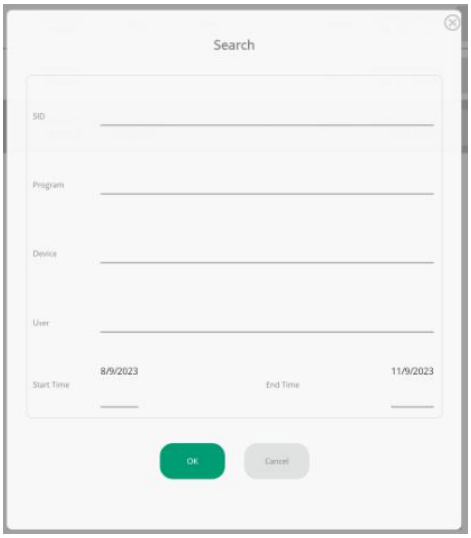


Figure 5-6 Result Search

5.4.2.4 Upload

After the IP address is correctly connected, select one or the above records and click "**Upload**" to upload the data to the LIS information management system. If the connection fails, click "**Upload**" and the pop-up window will prompt " the link to LIS failed"**.**

5.4.3 Setting

The setting interface is composed of **System Information, Language Setting, User Management, Modify Password, Test Script Management, PCR Script Setting, LIS Setting, Device Cascades, Sample Type, System Log, Help, Advanced Setting and Logout,** as shown in figure 5-7.

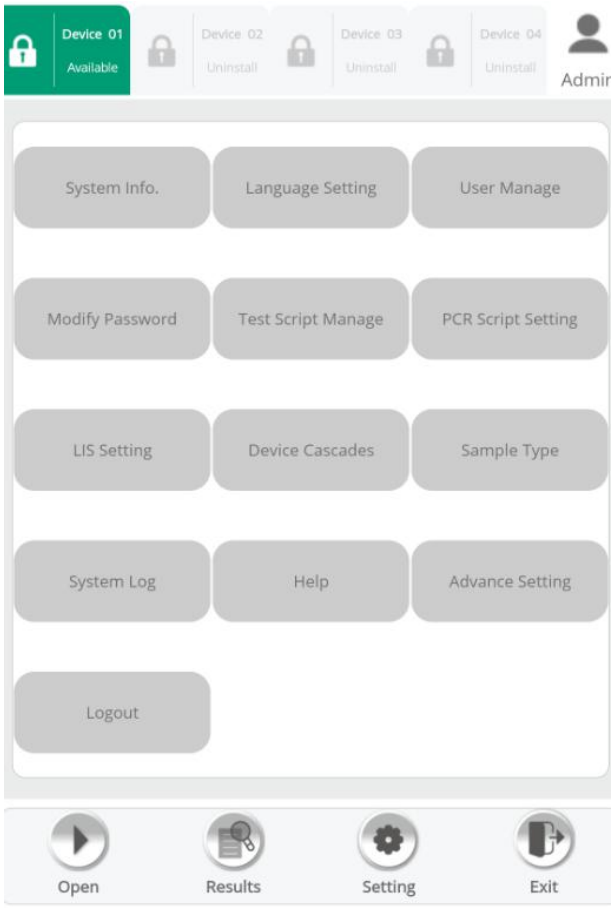


Figure 5-7 Setting Interface

5.4.3.1 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.

5.4.3.2 Language Setting

User could set system language as Chinese , English and Turkish, as shown in figure 5-8.

Figure 5-8 Language Setting

5.4.3.3 User Management

User is classified as **common user**, **admin** and **factory user**. The illegal user cannot log in the system software to operate the instrument. The user management interface is as shown in figure 5-9.

All three users could perform open/close compartment door and exit function. Besides that, they own the following different accesses.

- **Common User**: The common user could view his or her own account results data. The function of system information, language setting, modify password , LIS setting, system log, help, advanced setting and logout of setting interface can also be conducted by common user.
- **Admin**: Admin can view the result data of all accounts. Besides the above common user's accesses, admin also enjoys the function of Test Script Management, user management, PCR Script Setting, device cascades, sample type.
- **Factory User**: The factory user can view the result data of all accounts. The function of system information, Test Script Management, user management, language setting, PCR Script Setting, device cascades, LIS setting, sample type system log, help, advanced setting and logout.

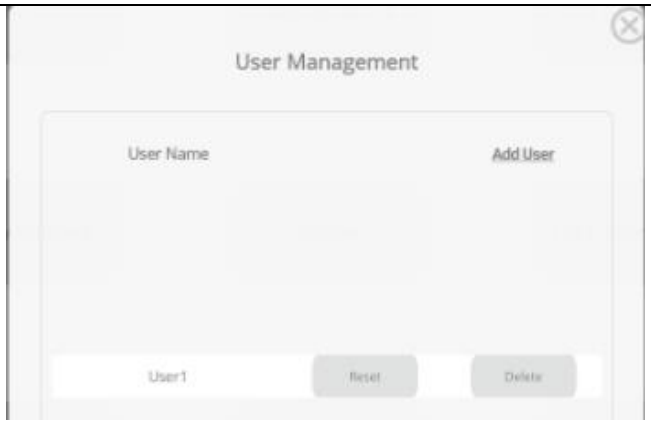


Figure 5-9 User Management

- **User Name**: The admin or factory user could view the users in the user list.
- **Reset**: Click **reset** after selecting a user and there pops up a window where prompts whether to reset the user. Click "**Yes**" to reset the password as 123456 while click "**No**" to cancel the reset operation, as shown in figure 5-10.

Figure 5-10 Reset User

- **Delete**: User could click **delete** key to delete the selected user in the list, as shown in figure 5-11.

Figure 5-11 Delete User

- **Add User**: This function key is for adding a user, as shown in figure 5-12.

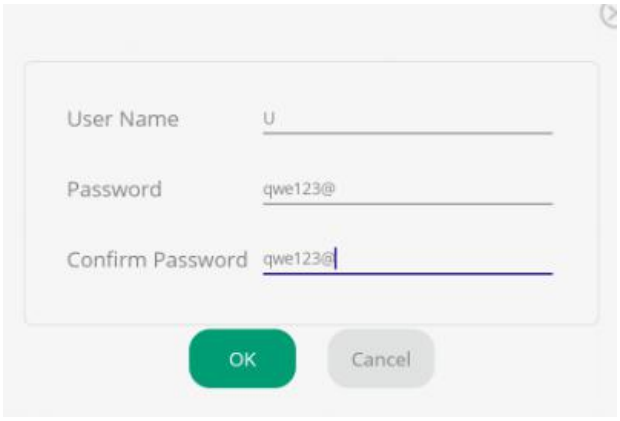


Figure 5-12 Add User

The new user name should be different with the existing user names and the character length should be less than or equal to 15. The new password characters shall be 6-20 with figure, letter and symbol allowed.

Warning: The factory user could reset the admin account password but cannot delete admin while the admin could only to reset and delete the common user account.

5.4.3.4 Modify Password

The current user's password can be modified here, as shown in figure 5-13.

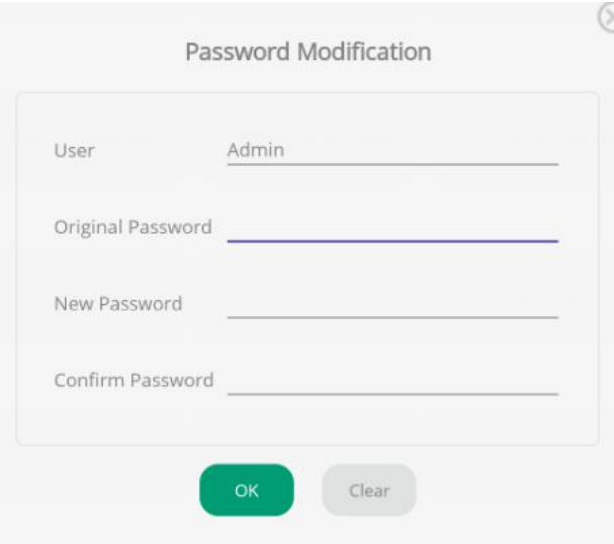


Figure 5-13 Modify Password

- **User**: It displays the currently logging in user by default.
- **Original Password**: Enter the original password correctly.
- **New Password**: Enter a new password whose format shall be same to the password in user management interface.
- **Confirm Password**: Enter the new password again.
- **Ok**: Click "**ok**" to complete password modification. If the original password is incorrect or the passwords confirmed are inconsistent, there pops up a window with "**Clear**" function that could clear the inputs.

5.4.3.5 Test Script Management

User could manage the detection script in Test Script Management interface, as shown in figure 5-14.

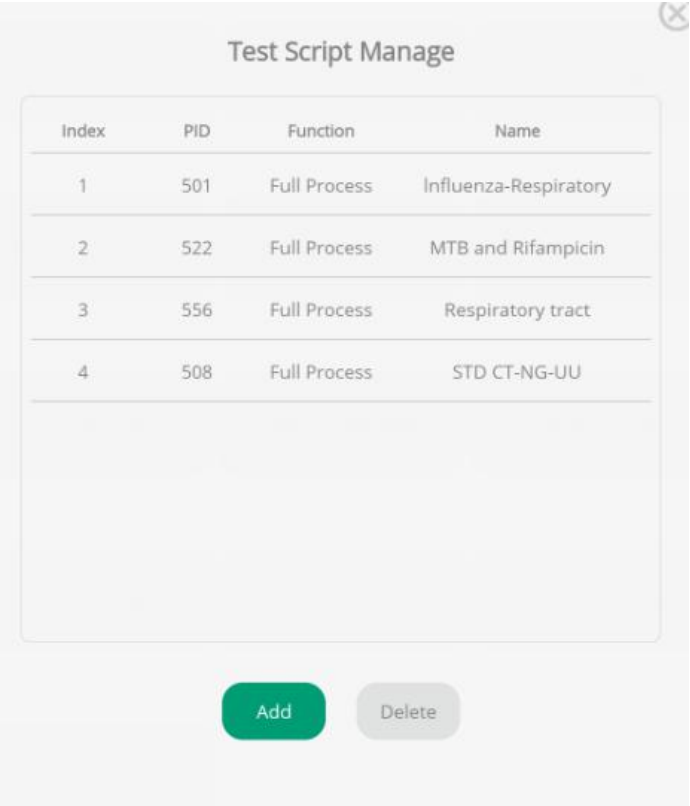


Figure 5-14 Test Script Management

- **Index**: The detection No. of the existing software.
- **PID**: It is the code marking the detection script.
- **Function**: It is the function marking the detection script, including extraction, PCR and whole process.
- **Name**: It is the name of detection script.
- **Add**: It displays the folder path after clicking this key, select the file suffixed with .sf and click "**Open**" to add a script.
- **Delete**: Select the script you want to delete from the script list, click "**Delete**", and a pop-up prompt will appear asking "**Delete: ***?**". Clicking "**Yes**" will delete the script and remove it from the list, while clicking "**No**" will cancel the deletion.

5.4.3.6 PCR Script Setting

User could modify the existed or new PCR script in the corresponding interface, as shown in figure 5-15.

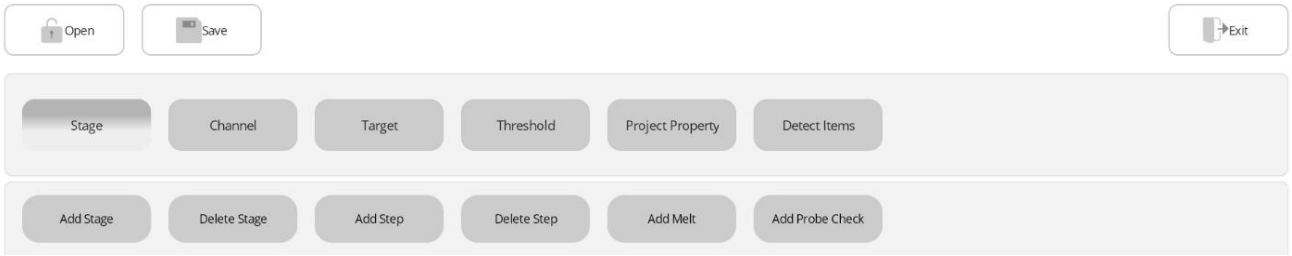


Figure 5-15 PCR Script Setting

- **Open**: This key to open the PCR script in the folder of Script.
- **Save**: This key is to save the opened or added PCR script.
- **Add Stage**: This is to add PCR stage.
- **Delete Stage**: This key is to delete PCR stage.
- **Add Step**: This is to add PCR steps.
- **Delete Step**: This is to delete PCR steps.
- **Add Melt**: This is to add Melting program.
- **Add Probe Check** : This is to add probe check program.
- **Channel**: This key is to check the selected fluorescence channel.
- **Target**: Users can add new targets based on the fluorescence channel of the PCR reagent to be added.
- **Threshold**: Users can modify or add the threshold value according to the fluorescent channel of the PCR reagent to be added.
- **Project Property**: This key is to add reagent type and detection type.
- **Detect Items**: Set the negative and positive interpretation according to the PCR reagent manual.
- **Exit**: This key is to return to software home page.

5.4.3.7 Device Cascade

Up to 4 instruments can be cascaded with one as the console. See Section “4.3.7 Instrument Cascade” for details.

5.4.3.8 LIS Setting

User could select the needed data, select the file format CSV and TXT, configure the data path, check “Auto-export” and click “Save”. Make sure to export the experiment data to LIS, as shown in figure 5-16.

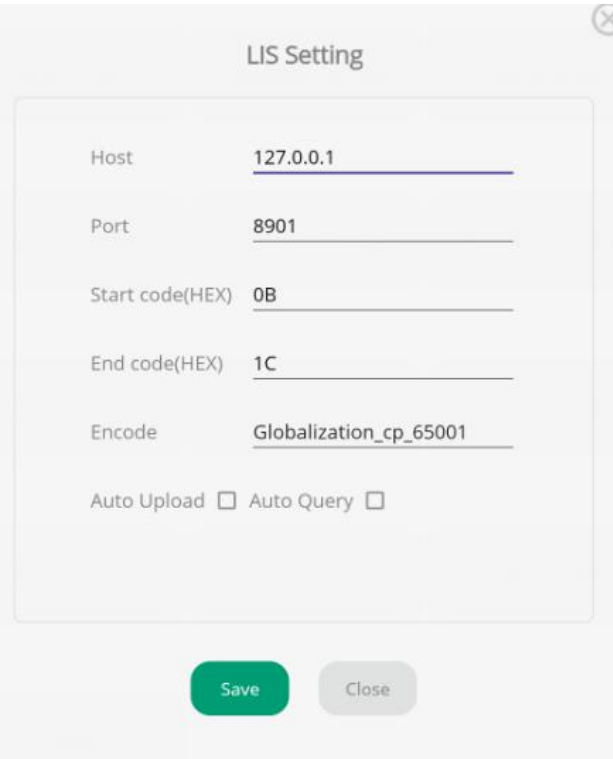


Figure 5-16 LIS Setting interface

[**Host**]: Default is 127.0.0.1, you can add the host IP address, it cannot be empty;

[**Port**]: Default is 8901, you can add the port;

[**Start code (hexadecimal)**]: Default is 0B:;

[**End code (hexadecimal)**]: Default is 1C;

[**Encode**]: Default is Unicode (UTF-8);

[**Auto Upload**]: After successfully connecting to the LIS system, check "**Auto upload**" and click the "**Confirm**" button. After the program is finished, the data will be automatically uploaded through the LIS server; if "**Auto upload**" is not checked, you can enter the historical data interface to manually upload the selected data. If the upload is successful, you can view the upload status of the corresponding data in the historical data list interface;

[**Auto Query**]: After successfully connecting to the LIS system, check "**Auto query**" and click the "**Confirm**" button. When running the program, enter the correct sample information (ID) and the corresponding patient number will pop up automatically. If you enter the wrong sample information (ID), the interface prompts "No patient information found"; if "**Auto query**" is not checked, the patient number will not be recognized when running the program.

5.4.3.9 Sample Type

User could enter the new sample information like oropharyngeal swab and click “**Add**”. The new sample type is added and saved in “**Type**” and user could select sample type in “**Sample Details**”.

5.4.3.10 System Log

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

5.4.3.11 Help

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

5.4.3.12 Advanced Setting

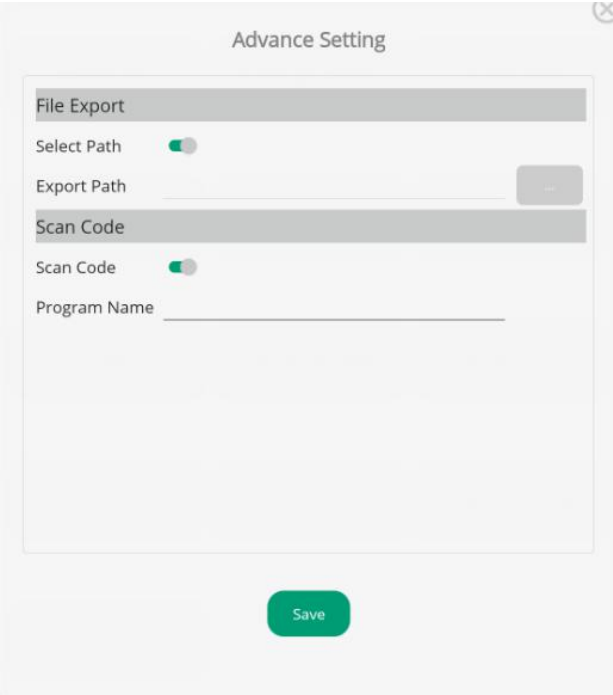


Figure 5-17 Advanced settings interface

- **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.

5.4.3.13 Logout

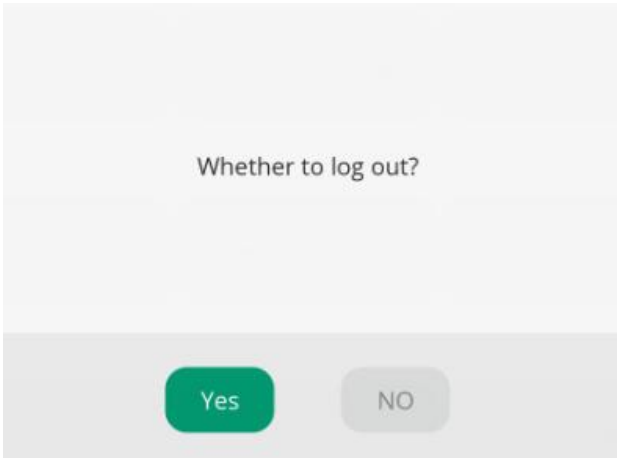


Figure 5-18 Logout

Click “**Logout**” and the prompt “**Whether to log out?**”, select “**Yes**”, then log out of the current user and switch to the software login interface; Select “**No**” and the popup window disappears.

5.4.4 Running

After the user enters the sample information, scans the QR code of the iCassette, and properly positions the iCassette and tray into the compartment, clicking the "**Start Running**" button will initiate the procedure. For details, refer to Sections 6.5 to 6.8.

5.4.5 Software Logout

After the run is completed, click the "**Exit**" button to exit the system software, , as shown in figure 5-19.

Upon clicking, a confirmation dialog will prompt "**Are you sure to quite system software?**". Clicking "**Yes**" will exit and close the system software, while clicking "**No**" will only dismiss the confirmation prompt and retain the software interface.

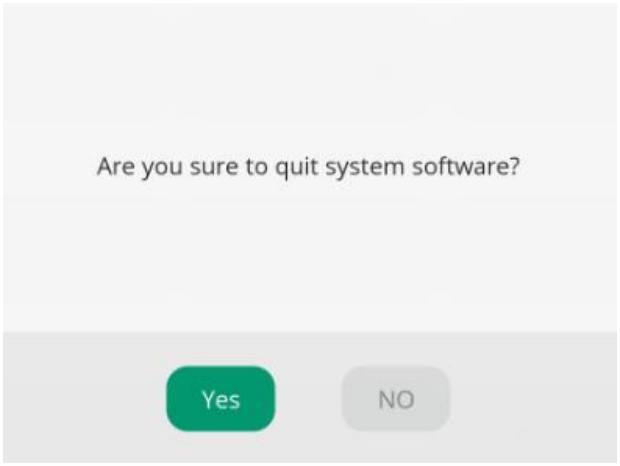


Figure 5-19 Software Logout Window

User could check the operation logs under the catalog **DataLog** folder where records the key operation information.

6 Operating Introductions

6.1 Overview

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

6.2 Section Guide

Steps	Procedure	Section
1	Software Login	Section 6.3
2	Instrument Self-inspection	Section 6.4
3	Specimen Pretreatment and Addition	Section 6.5
4	Information Entry and Verification	Section 6.6
5	Loading iCassettes into the iCassette Tray	Section 6.7
6	Loading iCassette Tray into the Compartment	Section 6.8
7	Initiating the Program	Section 6.9
8	Monitoring the Process	Section 6.10
9	Removing iCassette Tray from the Compartment	Section 6.11
10	Viewing and Interpreting Results	Section 6.12

6.3 Software Login

Follow these steps to log into the software:

(1) Plug the instrument into a power source and turn on the power switch located at the back of the instrument.
(2) Press the instrument switch for 1 second to power on the instrument.
(3) Open the Galaxy Neo system software.
(4) Log in with the correct username and password.
(5) After a successful login, the initial interface will be displayed.

6.4 Instrument Self-Inspection

The instrument performs automatic self-inspection as follows:

(1) Initialization:

All mechanical structures are reset to their initial positions.

A prompt window will appear, displaying the initialization progress.

(2) Self-Inspection:

Functional components undergo a full self-inspection.

The software will display corresponding prompts during the process.

⚠ **Warning**: During the self-check process, the sample compartment door will automatically open and then close. This process is a normal self-check process. Please do not touch the iCassette Tray with your hand or pull it out forcibly. Or hands may be pinched, resulting in your disability or damage to the instrument.

⚠ **Warning**: Do not place the iCassette tray into the instrument during the self-check procedure, as this may cause damage to the device.

6.5 Specimen Pretreatment and Addition

Perform the following:

- Follow the reagent(iCassette kit) instructions for specimen pretreatment (if applicable).
- Add the sample to the iCassette as directed.
- After completing these steps, proceed to Section 6.6 for information entry and verification.

6.6 Information Entry and Verification

- **iCassette Tray Numbering**

The iCassette tray slots are numbered from left to right (1 to 2), as shown in Figure 6-1.

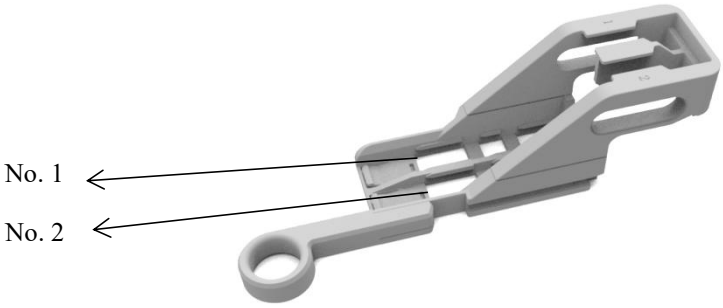


Figure 6-1 iCassette Tray Numbering

- **Entering Sample Information**

1. Click “ ” to enter patient information, input sample concentration, and select the sample type.
2. Click the “ ” icon to scan the barcode of the sample.

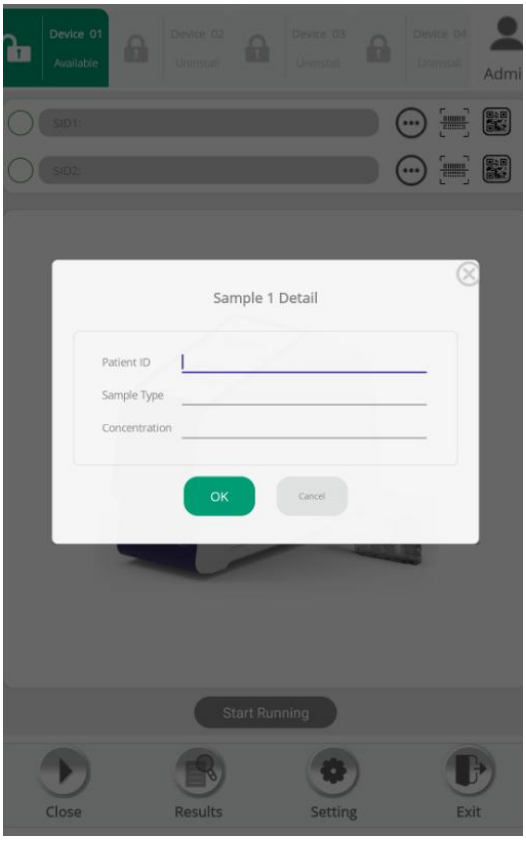


Figure 6-2 Enter sample information

3. Click “ ”, and align the QR code on the iCassette with the scanner. After scanning, a pop-up message will appear prompting: “**Please confirm the program: *****” (where *** represents the program name, as shown in Figure 6-3. The image is for reference only; please refer to the actual program name). At this point, click “**Yes**” in the pop-up window. A second prompt will appear: “**Do you need to scan a second iCassette?**” (as shown in Figure 6-4). Click “**No**” to cancel the operation.

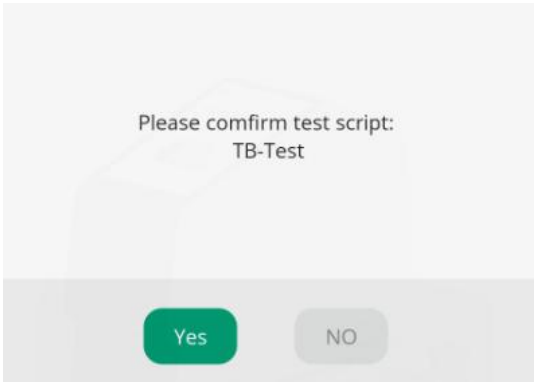


Figure 6-3 Confirm Test Program

4. When the pop-up message prompts “**Do you want to scan the second sample?**”, click “**Yes**”, then click the “ ” icon on the second sample slot to scan the QR code of the second iCassette. After the scan is completed, the instrument will automatically open the chamber. If you click “**No**”, the device will open the chamber automatically. Once the chamber door is fully opened, you may insert the iCassette tray loaded

with the test cassette to proceed with the next step.

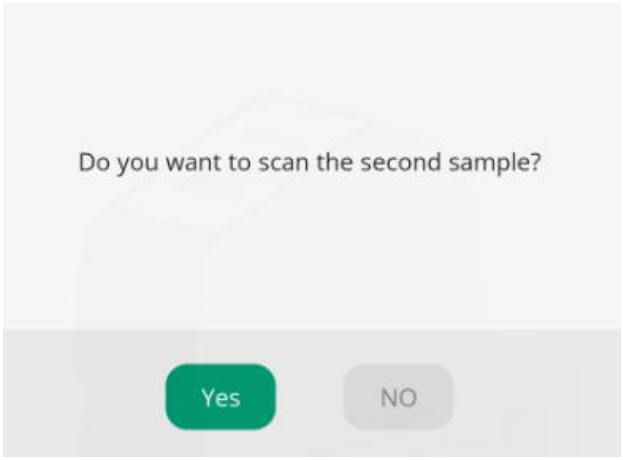


Figure 6-4 Do you want to scan the second sample?

Warning: To proceed with the testing program, QR code scanning is mandatory for all test channels containing test iCassettes. The iCassettes correspond to positions 1 through 2, arranged from left to right of the iCassette tray.

6.7 Loading iCassettes into the iCassette Tray

After the instrument completes QR code scanning, load the test cassette into the tray by following the steps below:

1. Retrieve the test iCassette from appropriate storage conditions.
2. Insert the test iCassette into the iCassette tray along the guide grooves at the bottom.
3. Ensure the test iCassette is fully inserted into the iCassette tray.
4. Confirm that the test iCassette is securely seated in the tray without shaking or loosening.

6.8 Loading the iCassette Tray into the Compartment

- Follow the steps below to load the iCassette tray into the instrument:

1. Place the iCassette tray loaded with the test iCassette into the Compartment's tray holder.
2. Align the iCassette tray with the guide grooves of the holder and insert it fully until it cannot be pushed further.

Warning: Ensure that the iCassette tray is properly and completely inserted into the tray holder to avoid operational errors during chamber loading or program execution.

6.9 Initiating the Program

Starting the Test

(1) After loading the test iCassette and inserting the iCassette tray, follow the steps below to start the run:

Click “Start Running”. The instrument Compartment chamber door will close automatically.

Note: The “Start Running” button is enabled only after QR code scanning is completed; before scanning, the button remains greyed out and inactive.

(2) A system pop-up will appear: “iCassette position checking” (see Figure 6-5).

If the number or position of the test cassettes in the tray does not match the scanned information, a warning will appear: “Device 1 iCassette position and scanned barcode position unMatch, please confirm!”(see Figure 6-6).

Figure 6-5 Detecting iCassette positions

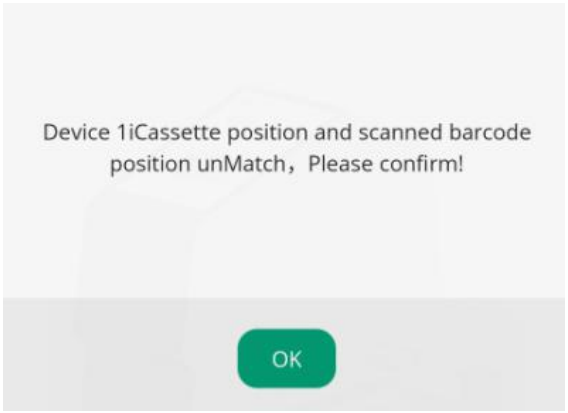


Figure 6-6 Mismatch Between Test iCassette Quantity or Position and Scanned Sample Slots

(3) Once the test cassette verification is complete, the software will initiate the fully automated workflow, and the instrument will begin executing the test program.

(4) Click “Stop Testing” to halt the currently running test program.

6.9.1 Automated Full Workflow

① If the user needs to perform the automated full workflow, a pop-up message will appear: "Please confirm the program: ***", where *** represents the program name (see Figure 6-3; the image is for reference only, and the actual program name should be based on the running program).

② Click “Yes” then correctly scan and place the test iCassette as prompted by the system. After that, click “Start Running” to begin.

③ Click “No” to cancel the operation.

6.9.2 Nucleic Acid Extraction

① If the user needs to perform nucleic acid extraction, after a successful scan, a pop-up message will remind the user to choose between “Extraction” and “PCR” functions.

② Click the “Extraction” button to start the nucleic acid extraction process.

③ Click “Cancel” to stop the process.

④ If the user only needs nucleic acid extraction, after the extraction process is complete, simply remove the PCR tube to obtain the required nucleic acid.

Figure 6-7 Function selection "Extraction Purify” “PCR”

6.9.3 PCR

① Before starting the PCR process on the Galaxy Neo instrument, the user needs to edit and save the PCR program according to the experimental requirements.

② For details on how to set up the PCR program, refer to Chapter 5, “5.4.3.6 PCR Program Settings.”

③ The user should prepare the PCR test cassette and PCR tubes, fill the PCR tubes with reagents, and then securely tighten the PCR tubes onto the PCR consumable rack.

④ Load the PCR consumable rack into the tray.

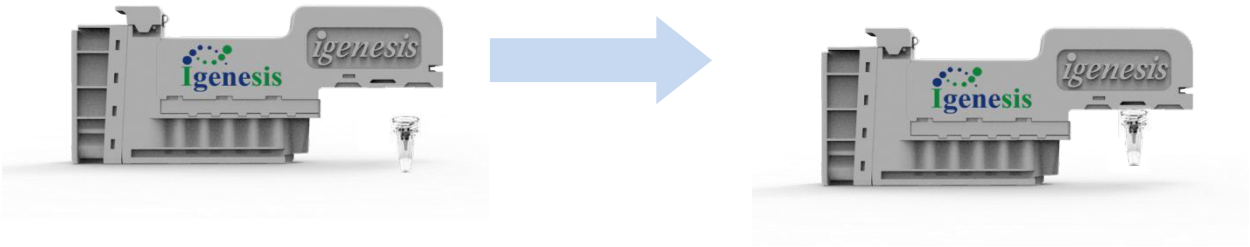


Figure 6-8 Schematic Diagram of PCR Tubes Loaded onto the PCR Test Cassette

⑤ If the user needs to perform the PCR process, after a successful scan, a pop-up message will prompt the user to choose between “Extraction” and “PCR” functions.

⑥ Click the “PCR” button, and as shown in Figure 6-9, select the PCR program to be executed.

⑦ Click “OK” to start the selected PCR process.

⑧ Click “Cancel” to stop the process.

Figure 6-9 PCR program selection

⑨ After completing the nucleic acid extraction in Section 6.9.2 and obtaining the nucleic acid, the user can adjust the nucleic acid volume and add PCR reagents as needed for the PCR reaction.

⑩ Repeat steps 6.5 to 6.8 (Loading the tray with the test cassette → Entering sample information → Loading

the tray into the chamber → Starting the run).

⑪ After a successful scan, the user selects the “PCR” button.

⑫ Select the desired PCR program and begin the PCR process to complete the PCR operation.

6.9.4 Integrated PCR Reagent Testing

The Galaxy Neo instrument, when used in conjunction with the Galaxy TPT test cassette, supports the integration of third-party PCR reagents. The operation steps are as follows:

① If the user intends to run the automated workflow with third-party PCR reagents, the PCR tubes on the Galaxy TPT test cassette must be manually removed.

② Fill the PCR tubes with the required third-party PCR reagents.

③ Securely tighten the reagent-filled PCR tubes back onto the test cassette.

④ Load the test cassette into the tray.

⑤ Follow steps in Sections 6.5 to 6.8 (Tray Loading → Sample Information Entry → Tray Insertion → Start Testing).

⑥ After a successful scan, a pop-up will prompt: “Please confirm the program: ***,” where *** represents the program name.

⑦ Click “Yes” to initiate the automated full workflow.

⑧ Click “No” to cancel the operation.

6.10 Monitoring the Process

Once the test program is initiated, the system displays the real-time operation interface, providing information on the current progress, remaining time, cassette position, and dynamic visualization of the PCR process.

Users can determine the current status of the experiment by referring to the animated diagram of the test cassette movement or the PCR workflow stage, as illustrated in Figures 6-10 and 6-11.

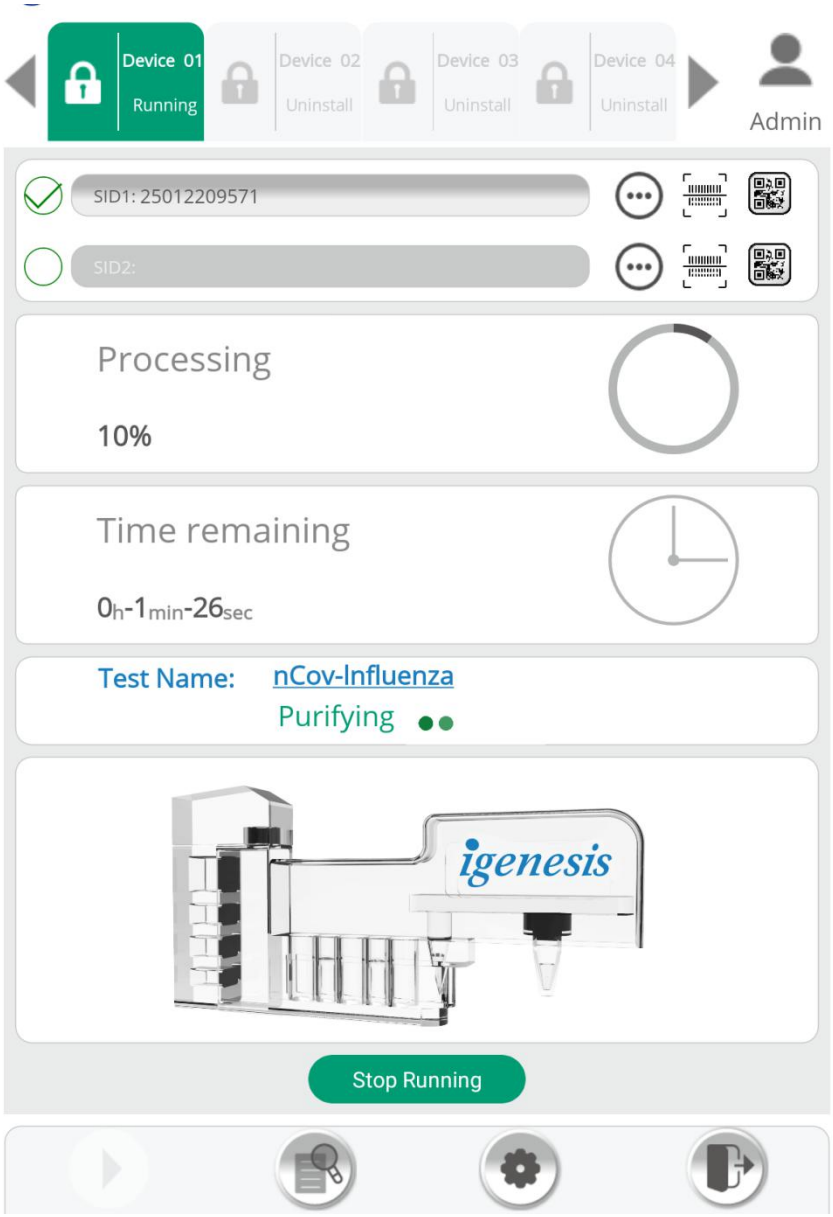


Figure 6-10 Program Monitoring Interface

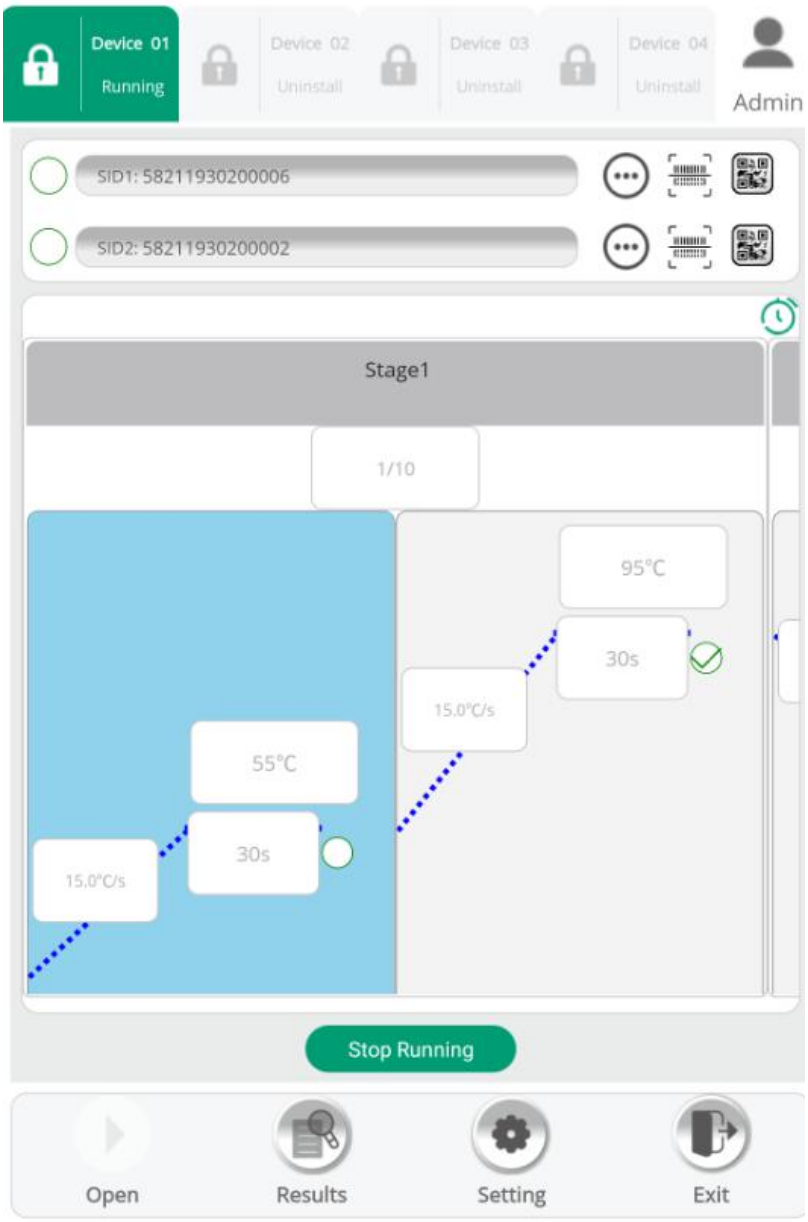


Figure 6-11 PCR runtime dynamic diagram

- **Processing**: It displays the program progress.
- **Time remaining**: This is the time remaining of the program.
- **Test name**: The current running process category.
- **PCR runtime dynamic diagram:** When running to the PCR stage, the real-time running status of the program can be displayed.

6.11 Removing the iCassette Tray from the Compartment

When the program is completed, there pops up a window about iCassette Tray out of the compartment, as

shown in figure 6-12.

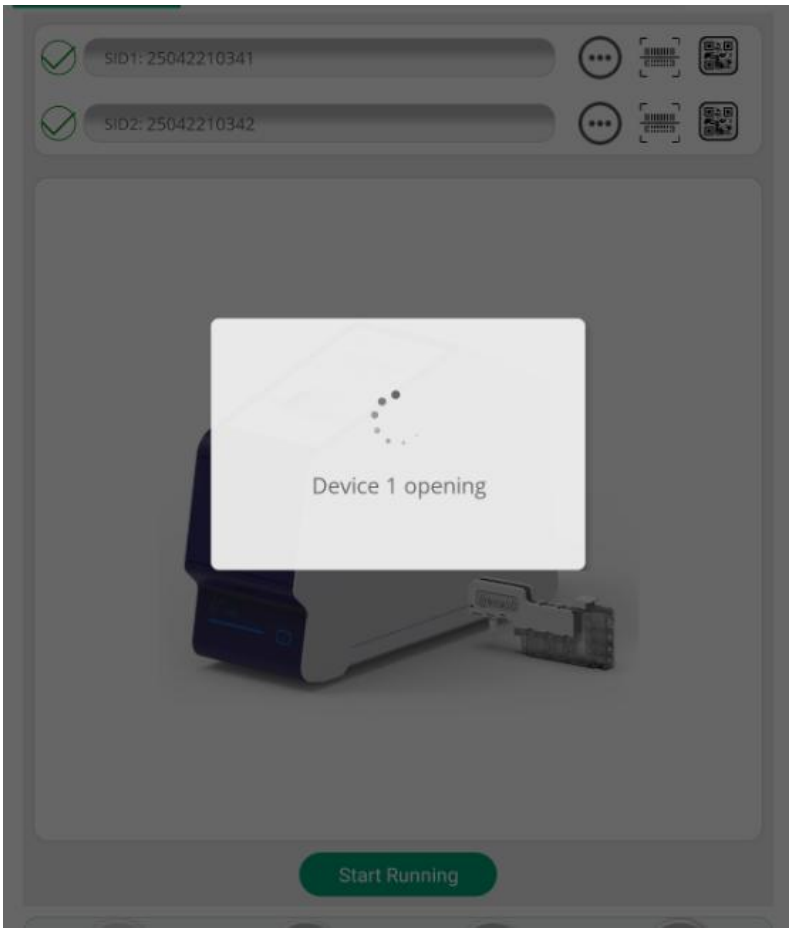


Figure 6-12 iCassette Tray out of Compartment

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.

6.12 Viewing and Interpreting Results

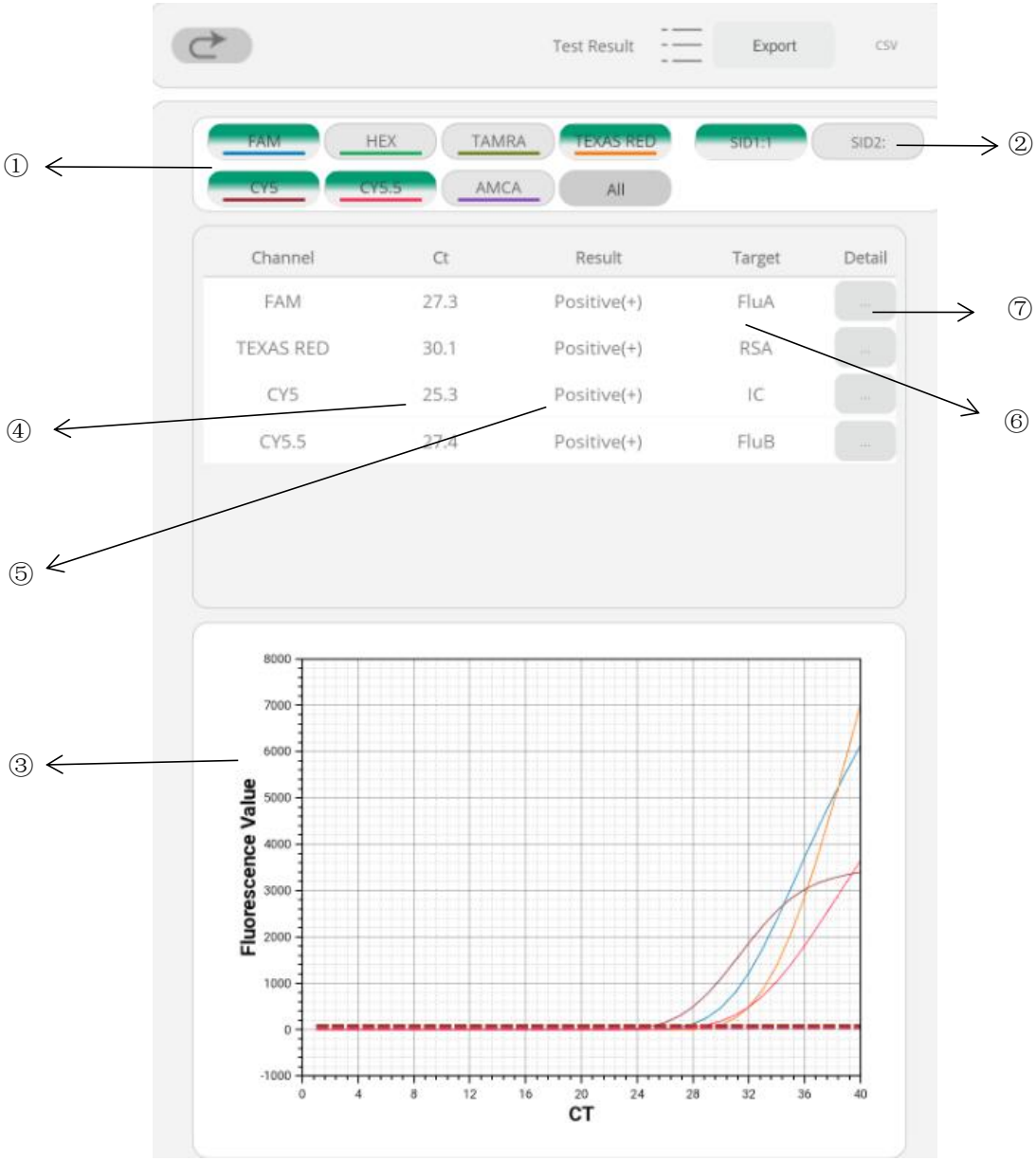


Figure 6-13 Experiment Result Viewing

① **Fluorescence Channel:** All fluorescence channels of the currently selected sample are FAM, HEX/VIC, TAMRA /NED, ROX/TEXAS RED, CY5, CY5.5 and AMCA, and users can freely choose to view the amplification results of any fluorescence channel.

② **Select Sample:** Click to select the channel and click again to cancel the selection. The sample result table will display the selected sample's name, fluorescence channel, threshold value, Ct value;

③ **Amplification Curve:** The amplification curve in the figure is the amplification curve of the corresponding fluorescence channel of the selected sample.

④ **Ct:** Ct value, the number of amplification cycles when the amplification product reaches the threshold during PCR amplification.

⑤ **Result**: Negative and positive.

⑥ **Target:** Target gene or fragment.

⑦ **Data Details:**

(1) **Patient ID:** You can enter the patient information corresponding to the iCassette.

(2) **Sample Type:** The sample type can be selected according to the actual situation.

(3) **Sample concentration:** Displays the concentration information of the current sample.

(4) **Standard Curve:** Determine whether this data is standard curve data.

(5) **Fluorescence channel:** The fluorescence channel of the currently selected sample.

(6) **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.

(7) **Increment**: The fluorescence signal value after PCR amplification.

(8) **Melting threshold:** Set the fluorescence intensity standard for the melting curve;

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

(10) **Melt Result:** The results were negative, positive and corresponding virus types.

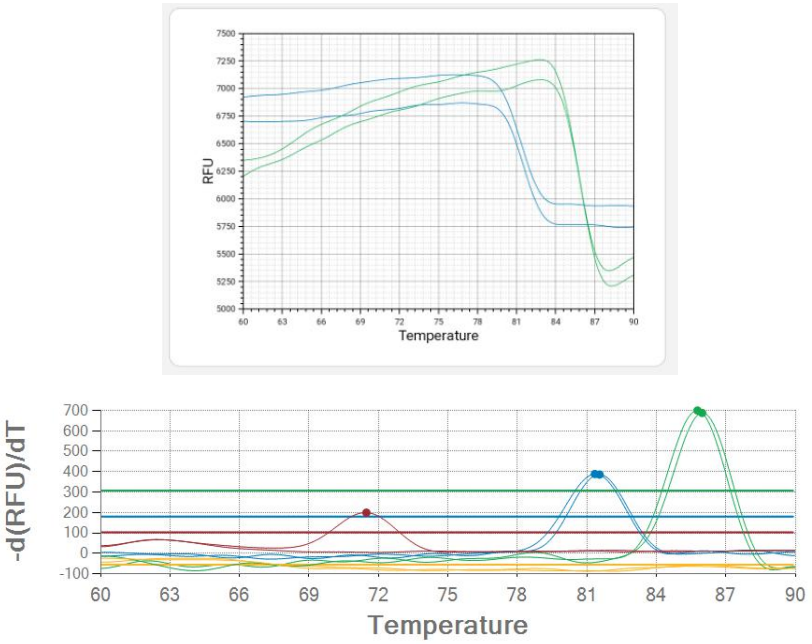


Figure 6-14 Result Viewing – Melting Curve

7 Calibration and Quality Control

7.1 Overview

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

7.2 Calibration

The user does not need to calibrate the Galaxy Neo instrument. Igenesis has performed all necessary calibrations before the user receives the Galaxy Neo 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 Neo 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 Neo 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 Neo 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 iCassette

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

⚠ **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 iCassette 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 Neo 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 Disinfecting and Cleaning	Section 9.3
iCassette Tray Holder Cleaning	Section 9.4
iCassette Tray Cleaning	Section 9.5

9.3 Instrument Disinfecting and Cleaning

Warning: To prevent electric shock, ensure the device is powered off and disconnected from the power supply before performing disinfection and cleaning.

Warning: The device must be disinfected prior to cleaning.

Warning: If hazardous substances leak onto the instrument tray surfaces or into the device interior, it is recommended to immediately proceed with the following disinfection steps.

Warning: If hazardous materials contaminate the equipment surface or penetrate internal components, appropriate disinfection procedures should be implemented.

Warning: Do not use cleaning or disinfecting agents that may cause hazardous chemical reactions with device components or materials within the equipment.

Warning: If uncertain about the compatibility of disinfectants/cleaners with device parts or internal materials, consult the manufacturer or authorized representative for guidance.

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.

9.4 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 power 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 Neo instrument or enter the interior of the instrument, the following

disinfection methods should be adopted.

9.5 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.

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
The system cannot be started.	1. The instrument is not connected to a power adapter. 2. The instrument AC power switch is not on. 3. The instrument power in the front is not pressed properly. 4. The instrument still cannot be started after trying the above 4 steps.	1. Plug the instrument to the power adapter. 2. Turn of the power switch at back of the instrument. 3. Press the instrument switch 1 second till the indicator light is on. 4. Please contact the after-sale service..
User name or password is not correct.	Enter a wrong user name or password.	Please contact the admin for the right user name and password.
Errors occur when self-inspection.	1. iCassette Tray in the instrument when self-inspection. 2. The hardware error is reported by mistake or the hardware is damaged.	1. Please do not put the iCassette Tray in the instrument when the experiment is not run. 2. Please unplug the instrument and log in the system software again. If the problem is not solved, please contact the after-sale service.
When entering the compartment, the iCassette Tray is jammed or bumped.	1. The iCassette Tray or the reagent kit on the iCassette Tray is not loaded properly. 2. The reagent kit is not loaded in position.	1. Reload the iCassette Tray or reload the reagent kit on the iCassette Tray properly. 2. Reload the reagent kit.
It prompts user to enter SID information.	The SID information is not entered in the corresponding channel where loads reagent kit	The SID information shall be entered in the corresponding channel where loads reagent kit.

The motor does not arrive in the sensor position.	1. Motor or sensor errors. 2. The mechanical part interferes.	Please contact the after-sale service if the problem is not solved after reboot.
Motor errors	1. The sensor errors. 2. The mechanical part interferes.	Please contact the after-sale service if the problem is not solved after reboot.
The heating tip errors	1. Errors reported by mistake. 2. The heating module is damaged.	Please contact the after-sale service if the problem is not solved after reboot.
The reagent kit cannot scanned.	1. The reagent is not loaded into the iCassette Tray. 2. The reagent kit QR code is lost or unclear.	1. Please load the reagent kit into the iCassette Tray. 2. Change a new reagent kit or contact after-sale service.
The reagent kit type is inconsistent.	The reagent kit of the inconsistent PID kind code is loaded into the iCassette Tray.	Please load reagent kit whose PID kind code is consistent.
There is no matched program.	The PID kind code of the reagent kit used cannot be identified.	Please contact the after-sale service to handle it.
The reagent is non-effective.	1. The reagent kit is invalid. 2. The time of the computer is wrong.	1. Please use the valid reagent. 2. Please ensure the computer system time is right. If the problem is not solved, please contact the after-sale service.