Automated Fully Enclosed qPCR Instrument Galaxy Nano User Manual

User Manual Revision Time: June 20,2024

Version of User Manual: D/2

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

Manufacturer Address： Floor 3, Building 1, Lane 500, Furonghua Road, Pudong New Area, 201318 Shanghai, P. R. China.

Disclaimer and Copyright

Trademark Registration Statement:

Igenesis is the registered trademark of Igenesis (Shanghai) Co., Ltd.

Contact Information:

Igenesis (Shanghai) Co., Ltd.

Floor 3, Building 1, Lane 500, Furonghua Road, Pudong New Area, 201318 Shanghai, P. R. China.

Email Address: support@igenesisbio.com

Website Address: www.igenesisbioglobal.com

Postcode: 201318

Company Tel: +86-21-38016598

EC REP Lotus NL B.V.

Koningin Julianaplein 10, le Verd, 2595AA, the Hague, Netherlands

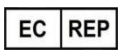
Email Address: peter@lotusnl.com

Tel: +31644168999

Labels on Transport Package

Label	Description
	**This Side Up**: It indicates the upward side of the transport package.
	**Keep Dry**: keep the transport package away from rain or any liquid.
	**Fragile**: The items inside are fragile, please handle with care.
	**Do not roll**: Please do not turn over the package.

Labels on Galaxy Nano

Label	Description
	**IVD Equipment**:Galaxy Nano belongs to In Vitro Diagnostic equipment.
	**Serial Number**: It indicates the serial number of this instrument.
	**Caution**: It indicates the “caution” of this instrument.
	**Manufacture Date**: It indicates the manufacture date of this instrument.
	**Consult Instructions for Use**: It indicates the consult instructions for the use of this instrument.
	**European Community Representative**: It indicates that the authorized representative of this instrument in European.
	**Manufacturer**: It indicates the manufacturer of this instrument.
	It indicates that the instrument meets the relevant standards.

Foreword

The User Manual of Galaxy Nano, an automated fully enclosed qPCR instrument (hereinafter referred to as Galaxy Nano instrument) gives a detailed description of safety use of the instrument. Please thoroughly read the User Manual and get familiar with relevant safety information before use. If the instrument is used before reading the user manual carefully and receiving professional training, personal injury may be caused and the instrument may be damaged, and consequently structural failure or data loss will be caused.

Service Life: 8 years. The service life of this product is determined by accelerated life test. Users should maintain and repair this product according to this user manual. This product that still remains basically safe and effective after maintenance and repair can be put into normal use.

Maintenance Period: Once every 12 months. Please contact Igenesis after-sales service for maintenance.

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.

Contents

1. Safety Instructions

Warning: Users must thoroughly read safety instructions before the use of Galaxy Nano instrument.

1.1 Warning Signs

The following signs will be shown in the user manual:

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 Nano 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 Nano may cause hands pinching.

The following signs will be shown on the instrument:

Sign	Title	Description
	Warning	On the appearance of the instrument;
	High Temperature	Near the heating module of the instrument;
	Biohazard	On the sample room of the instrument;
	Warning Hands Pinching	On the sample room of the instrument;
	IVD Medical Equipment	On the nameplate of the instrument;

Fig. 1-1 Labels On The Back

Fig. 1-2 Label On The Door Of Sample Room

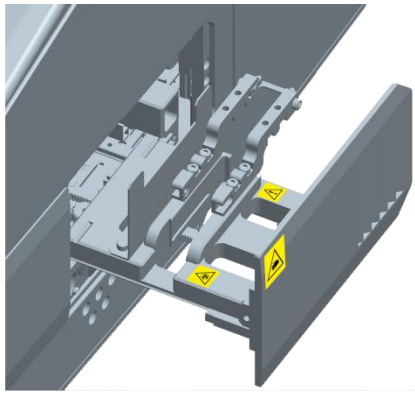


Fig. 1-3 Labels On The Sample Tray

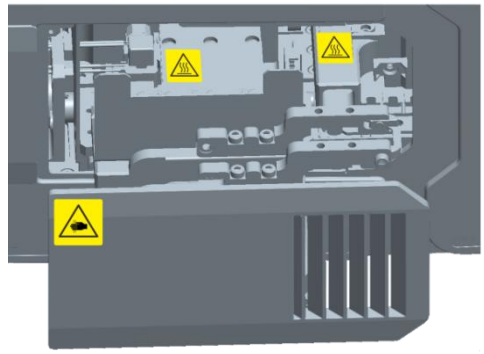


Fig.1-4 Labels On The Heating Module

Fig. 1-5 Label On The Upper Cover

1.2 Operation Requirements

Warning: The instrument is an electromechanical device. Users may suffer electric shock or hand injury and other potential hazards if it is not used in strict accordance with user manual.

- Strictly observe safety instructions on the instruments.
- If users fail to follow safety instructions, the system may be damaged, and consequently data loss or structural failure will be caused.
- Users shall not dismantle the instrument or replace other parts arbitrarily; otherwise damages thus incurred shall not be included in the warranty scope.
- The instrument must be maintained by professionals of the manufacturer only.
- The instrument must be installed indoors in a clean and well-ventilated place in order to avoid corrosive gas, high-intensity magnetic field interference, direct sunlight and intense light source and should be used under specified temperature and relative humidity.
- Working conditions for the instrument: indoor temperature is 15℃-35℃ and relative humidity is no greater than 85%.

Warning Hands Pinching: Do not touch the tray by hand when the sample room of Galaxy Nano instrument is opened and closed; otherwise hand injury will be caused.

Biohazard: Users must wear protective mask and gloves when disposing of toxic, corrosive or infectious substances. Users must observe relevant local safety specifications when disposing of or discarding toxic, corrosive or infectious substances. In case of splash or leakage, disinfect the contact part using suitable disinfectant, so as to avoid contamination of laboratory personnel and equipment. Damaged Galaxy Nano instrument must be returned to the manufacturer for repair and the surface must be disinfected before repair.

High Temperature: Do not touch the heating module when the instrument runs and soon after the instrument shuts down, so as to avoid scalding;

1.3 Electrical Safety

Warning: In order to avoid electric shock hazard, Galaxy Nano instrument must be connected to three-core grounded socket whose voltage is 220V (50Hz)(or 110V(60Hz)) in conformity with safety specifications and standards and matched three-core power cable must be adopted. Galaxy Nano instrument should be used in a

well-grounded place. Check whether the service environment is well-grounded when the instrument is installed, so as to avoid hazards.

- Ensure voltage and frequency of AC power supply conform to requirements before the instrument is connected to power line.
- Do not touch power switch and power line with wet hand.
- Do not unplug the power line before the instrument is powered off.
- Do not clean the instrument before it is powered off.
- Please turn off the power when the instrument is out of use.

Warning: In order to avoid shock hazard, the instrument must be connected to power supply with safety grounding device.

1.4 Electromagnetic Compatibility

Warning: The instrument meets the emission and immunity requirements specified in IEC 61326-2-6:2005.

- Galaxy Nano instrument should be used in the laboratory or test or measurement area with controlled electromagnetic environment and should not be used near strong radiation sources (such as unshielded radio source); otherwise normal use may be disturbed;
- The electromagnetic environment is proposed to be evaluated before use of the instrument;
- Galaxy Nano instrument is designed and tested as per class A equipment in GB 4824. Radio interference may arise from domestic use of the instrument, so protective measures should be adopted.
- It is a normal phenomenon that the screen of Galaxy Nano instrument flickers slightly when human body touches it, function and performance of the instrument will not be affected.
- Manufacturer is responsible for providing customers or users with electromagnetic compatibility information of the instrument;
- Users are responsible for creating an electromagnetic compatibility environment of the instrument, so as to ensure normal operation.

2. Overview

2.1 Automated Fully Enclosed qPCR System

Galaxy Nano instrument developed by Igenesis (Shanghai) Co., Ltd. (hereinafter referred to as Igenesis) is a new generation of automated medical qPCR analyzer which aims to provide safe and fast automated solutions for nucleic acid extraction and detection for IVD detection. Galaxy Nano is an automated fully enclosed fluorescence PCR instrument as shown in figure 2-1, which was launched by Igenesis in 2018 and can be used for nucleic acid extraction from many types of samples and real-time fluorescence PCR detection.

Figure 2-1 Galaxy Nano External View

2.2 Application Scope

Galaxy Nano can be used for real-time fluorescence PCR experiment and analysis. The instrument can be used in the laboratory or in a stable environment and together with corresponding reagent it can be used for fast and accurate qualitative of analytes (such as blood and body fluid) from patient's body or research on genetic typing, etc.

The IVDR Rule 5b applies to instruments specifically intended by the manufacturer for in vitro diagnostic procedures. These instruments are classified as class A.

2.3 Basic Principle

PCR principle is similar to the natural duplication process of DNA and the specificity depends on complementary oligonucleotide primers on both ends of target sequence. PRC comprises three basic reaction steps: degeneration, annealing and extension. With extremely high detection sensitivity, PCR can amplify target genes to be tested by millions of times 1-2h after circulating in the instrument.

Real-time fluorescence PCR means to add fluorescence labeling probe into PCR analysis system. The excited fluorescence signal value is proportional to the number of amplified genes. Quantitative determination of the template can be realized through real-time monitoring of the in vitro fluorescence value. Compared with ordinary PCR detection, real-time fluorescence PCR detection not only enables quantitative determination, but also has higher specificity and sensitivity.

2.4 Main Functions

Galaxy Nano is an instrument intended for real-time fluorescence PCR detection and integrating nucleic acid extraction, PCR amplification and fluorescence detection. It carries out nucleic acid extraction and amplification for the sample in a closed environment while detects the fluorescence growth amount inside the tube in real-time. After amplification, the system software automatically handles the experimental data, carries out quantitative and qualitative analysis and displays initial concentration and other experimental results of the test sample.

2.5 Basic Parameters

Fluorochrome	Fam, Hex, Tamra, Rox,/Texas Red, Cy5, Cy5.5, AMCA
Channel Fluorescence Detection Time	5s
Temperature Range	40℃-99℃
Temperature Control Precision	±0.5℃
Heating Rate (Max.)	≥2.5℃/s
Cooling Rate (Max.)	≥2.0℃/s
Fluorescence Intensity Detection Repeatability	CV≤3%
Sample Detection Repeatability	CV≤3%
Sample Linearity	R≥0.98
Fluorescence Linearity	R≥0.99
Input Power	12V 15A
Instrument Dimensions	435mm*175mm*285mm
Net Weight	9.5kg

2.6 Application Conditions

Galaxy Nano is for indoor use only.

- Operating Temperature: 15℃~35℃;
- Relative Humidity: 20%~85%;
- Power Requirements: 100-240VAC, 50/60Hz, 180VA;

- Atmosphere Pressure: 860hPa～1060hPa;

Running Environment:

- Hardware: 32 bite MCU Microprocessor;
- Network: Without connection;

Pad or PC running environment:

- Memory: 2GB or higher;
- Processor: Dual-core or higher;
- Software Configuration: Window 10, 64-bite operation system;
- 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.

Note: For cyber security, It is recommended that user should install security protection software.

2.7 Performance of Fluorescence Detection System

The configuration of detecting channel is followed:

Channel	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
Maximum Configuration	√	√	√	√	√	√	√
Standard Configuration	√	√	√	√	√	√	√
Dye	Fam	Hex	Tamra	Rox/Texas Red	Cy5	Cy5.5	AMCA
Light Source	Maintenance-free LED						

2.8 Instrument Features

- **Integration**: It is a fluorescence PCR instrument integrating nucleic acid extraction and PCR amplification.
- **Automation**: It is a full-automatic instrument except sample addition.
- **Miniaturization**: The instrument is as large as a computer host and it can save the limited desktop space.

2.9 Instrument Structure

Galaxy Nano comprises host, system software (Version: V2.3) and adapter. The host is composed of frame, X-axis and Y-axis mechanical motion module, temperature control module, magnetic stand, tray, optical module and electronic system module.

The function of each part is as following:

- **Host**: It conducts nucleic acid extraction and PCR amplification via control command.
- **System Software**: It is able to realize user management, cabin in, cabin out, procedure management, device diagnosis, PCR process control, optics data collection, result display, etc.
- **Adapter**: It serves DC power for the instrument.

2.10 Reagent Requirements

The system is an enclosed detection instrument that should be used together with matched detection reagent of Galaxy Nano. The other reagents or consumables are not matched with the instrument. If need purchasing, please refer to the *"Contact Information"* for help.

3. Instrument Installation

3.1 Transportation and Storage

The product must be transported with original package to avoid damage in accordance with requirements of order contract. The product should be stored at an environment temperature of -20℃-+50℃ with humidity of 20%-85% without condensation and should be free from corrosive gas during transportation.

Note: If the buyer needs to transport the instrument again after receiving the product from Igenesis, please disinfect and clean the instrument as Part 6.1 and 6.2 described and required.

- Please pack Galaxy Nano and its accessories into the package.
- Please well pack the instrument to avoid the collision during transportation.

Warning: If the instrument is damaged during transportation, please do not use it and contact the after-sales service .

Warning: Please keep the original package of the instrument for the future transportation.

3.2 Packing List

Please check out the packing list as blew.

No.	Name	Quantity.
1	Automated Fully Enclosed qPCR Instrument	1
2	Automated Fully Enclosed qPCR Instrument User Manual	1
3	Quick Guide	1
4	Warranty Card	1
5	Certificate of Quality	1
6	Power Supply	1
7	Power Cable	1
8	Communication Cable	1
9	PCR Tube Installation Tool	1
10	Pad Stand	1
11	Control Software (U Disk)	1
If missing parts and damaged parts are observed, please contact after-sales service immediately.		

3.3 Installation Requirements

⚠ **Warning**: Users must be trained by professionals or manufacturer or distributor before installing and using Galaxy Nano.

⚠ **Warning**: Galaxy Nano instrument cannot be used for domestic power grid and cannot be covered by anything.

Placement: Galaxy Nano should be placed far away from cold and hot air conditioner pipes and air outlets and should be free from direct sunlight. Please turn off the sample room when the instrument shuts down. The distance of Galaxy Nano to the objects or the wall shall be 20cm at least. Please do not block the air outlets.

Galaxy Nano instrument must be placed on a solid and horizontal platform with a bearing capacity of 20kg at least and must be free from direct sunlight.The instrument shall work at an environment temperature of 15-35℃ and at a relative humidity of 20- 85%.

3.4 System Installation

1st Step: Take out Galaxy Nano instrument from the packing box, place it in accordance with installation requirements in Part 3.3 and ensure the instrument and power socket are powered off.

2nd Step: Connect power adapter of DC 12V/15A output to the instrument as shown in figure 3-1.

Figure 3-1 Power Connection

3rd Step: Connect Galaxy Nano adapter to three-phase grounded socket.

Warning: In order to avoid electric shock hazard, the instrument must be connected to power supply with safety grounding device.

4th Step: Please install the pad holder properly on the instrument. If user uses his or her own computer, it needs to install the software on the computer. Double click "FTDIChip CDM DriverV2.08.30" and follow the steps to finish the system software installation after inserts USB flash drive into the computer. Then, find and double click "Nano. exe" to open it. Igenesis provides all the third-party software services within the product life cycle. If confronted with any problems on system software installation or instrument operation, please contact Igenesis after-sales service or the agent. It is recommended to install the antivirus software, cyber protection software and safety software (to avoid data leakage) on the PC or pad and to upgrade them regularly. Igenesis, or the authorized

personnel, conducts all the upgrade services about Galaxy Nano system software.

Note: It is better to close the account, communication port, shared file, service, etc, of non-medical intended use. Within Galaxy Nano life cycle, Igenesis could help to solve all problems related to cyber safety. If necessary, site service is also available.

5th Step: Press the key power switch of Galaxy Nano instrument and then of the pad. The instrument is turned on when the power switch key and "Screen" is lit up.

6th Step: Galaxy Nano instrument will enter the login interface after startup and then the instrument will carry out self-check. Users should observe and check the following points when the instrument carries out automatic self-check:

a. Communication link of the system is connected normally and display of menu bar in the main interface is normal (no grayish white keys in the menu bar), as shown in figure 3-2.

b. No errors are observed during and after self-check and users can use the instrument normally.

⚠ **Warning**: If the instrument fails to carry out self-check or errors are observed during self-check, please contact after-sales service immediately.

Figure 3-2 Main

4. Operation Instructions

4.1 Standard Workflow

Standard workflow of Galaxy Nano is shown below:

Step	Workflow	Section
1	Instrument Connection	4.2.1
2	Instrument Power On	4.2.2
3	System Software Startup	4.2.3
4	User Login	4.2.4
5	Sample Tray Ejection	4.2.5
6	Sample Tray Injection	4.2.6
7	Instrument Run	4.2.7
8	Automated Processing	4.2.8
9	Result of Processing	4.2.9
10	End of Operation	4.2.10

Warning: Do not turn off the power of Galaxy Nano instrument until the experiment is completed.

Warning: Users of Galaxy Nano shall be trained by professionals of manufacturer or distributor before installing and using the system.

Warning: The instrument shall be maintained by professionals of the manufacturer and shall be dismantled by maintenance personnel of the manufacturer, or any damage will not be covered by the warranty.

4.2 Instrument workflow

4.2.1 Instrument Connection

The pad used on the instrument shall be in conformity with IEC 60950-1. Please load the pad into the dedicated holder and then connect the holder with pad to the instrument via the dedicated cable.

4.2.2 Instrument Power On

Main power switch of Galaxy Nano instrument is right ahead of the instrument. Press the instrument switch over1 second and the blue light is on, which means the instrument is turned on. Press it again over 5 seconds, the blue light is off, which means the instrument is turned off.

4.2.3 System Software Startup

Note: Please turn on the instrument before software startup.

After turn on pad and start system software, Galaxy Nano system software will enter the login interface, as shown in figure 4-1.

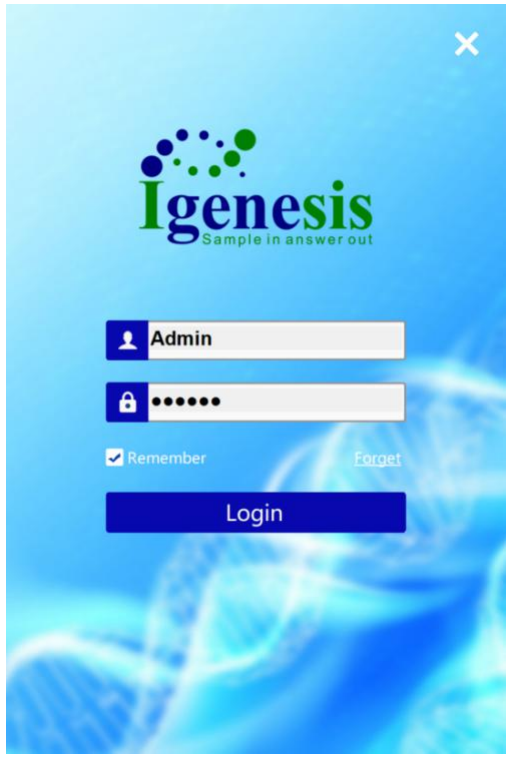


Figure 4-1 Login Interface

4.2.4 User Login

- If is not a new user, he or she could enter username and password to log in.
- If is a new user, he or she could log in by admin account. The username is Admin and initial password is 123456.
- The system will carry out “Self-check” after startup and login. If user receives warnings, please refer to *Appendix 1 Troubleshooting.*

- If there are no any errors(refer 4.3 6th Step), the software will display the initial interface, as shown in figure 4-2.

Figure 4-2 Initial Interface

Note: For password modification, please refer to **Modify Password** in Part 5.6.2.

Warning: The sample room door will be opened randomly and automatically and will be closed after a while during self-check. It's a normal self-check process, and don't touch the tray or pull it out forcibly by hand; otherwise hand injury may be caused or the instrument may be damaged.

4.2.5 Sample Tray Ejection

- User could click **Open** in the main interface to eject the Sample tray.
- Load the dedicated icassette(icassette is consumbal of Galaxy Nano):
  - Push the icassette into the sample tray with icassette bottom close to the tray bottom.
  - Please ensure the icassette is accurately inserted into the slot of the tray, as shown in figure 4-3.

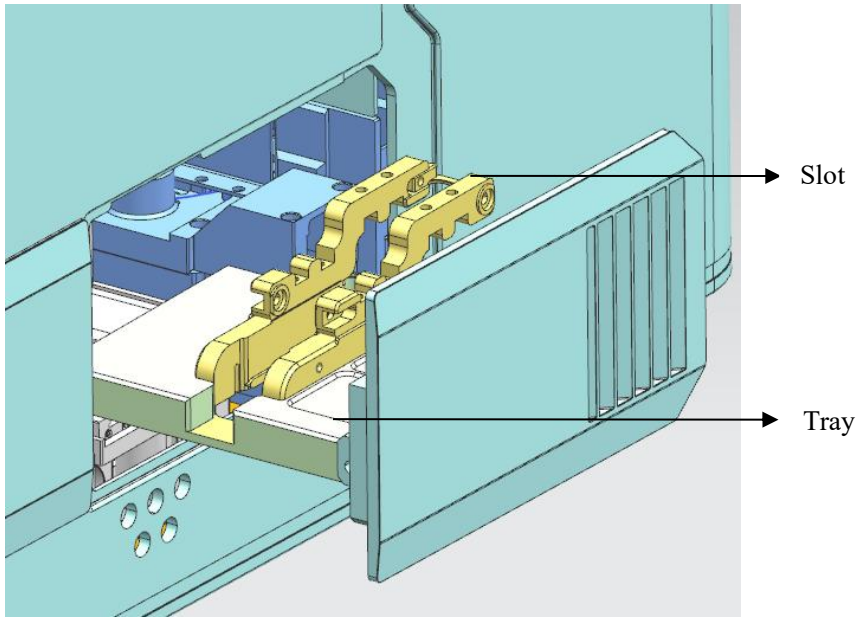


Figure 4-3 Sample Room

4.2.6 Sample Tray Injection

User could click **Close** to close Galaxy Nano Sample Room.

⚠ **Warning**: Please do not touch the tray when the Sample Room is opening and closing, otherwise hand injury may be caused.

4.2.7 Instrument Run

Galaxy Nano instrument will run automatically after user click **Run** in the main interface.

Galaxy Nano instrument will scan QR code of the icassette during sample tray injecting automatically.

iCassette QR code includes the following information:

- Reagent type;
- Serial number;

User may receive warning messages under the following situations:

- "iCassette unmatched" will be reported if the reagent mismatches the instrument.
- "iCassette error" will be reported in case reagent code error is observed and cannot be identified.

The instrument will stop running if warning message is observed. Users should check the information and replace the iCassette referring to *Appendix 1 Troubleshooting*.

Galaxy Nano instrument will revoke the processing program automatically after it detects the matched reagent (built-in processing program for the reagent) and process the iCassette. For purchase and upgrade of reagent type, please refer to Part 4.5 Purchase of Reagent Program.

4.2.8 Automated Processing

Galaxy Nano instrument displays the experiment progress so user could well schedule his or her work, as shown in figure 4-4.

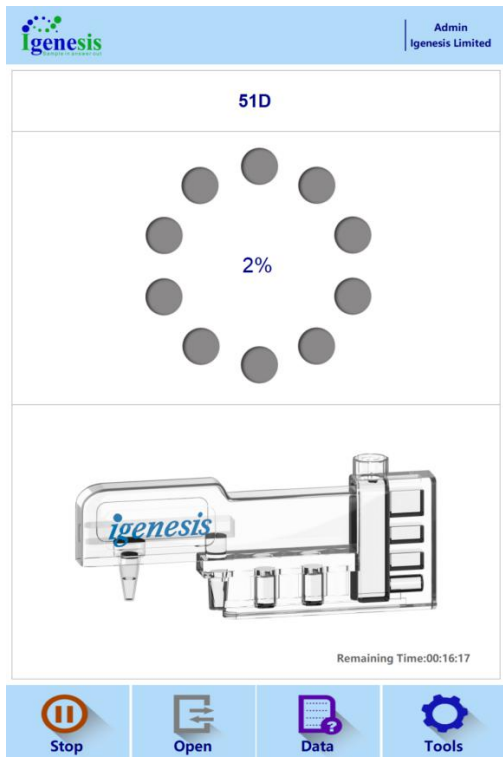


Figure 4-4 Running Interface

If there is no PCR Data after procedure is completed, the interface will turn to the initial interface, as shown in figure 4-2, or it will switch to result interface. The system software will initialize the program after procedure completed and inquire user eject sample tray or not, as shown in figure 4-5.

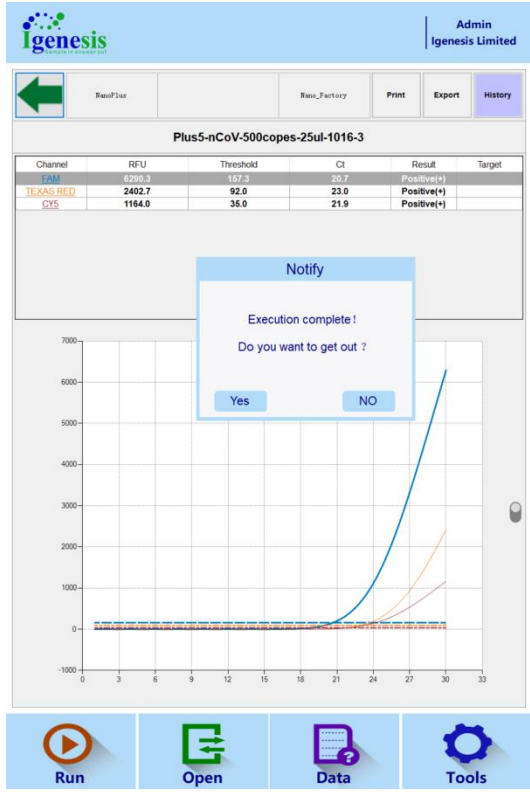


Figure 4-5 Sample Tray Ejection Query

The instrument may malfunction if misoperation is observed. If the malfunction occurs, please turn off the power for emergency stop and contact after-sales service.

4.2.9 Result of Processing

Galaxy Nano instrument will display different results according to reagent type after processing completed, as shown in figure 4-6.

If the reagent is intended for PCR amplification, Galaxy Nano instrument will display the final PCR amplification curve, increment, threshold value, and Ct value. If the reagent is intended for nucleic acid extraction only, Galaxy Nano instrument will return to the initial interface.

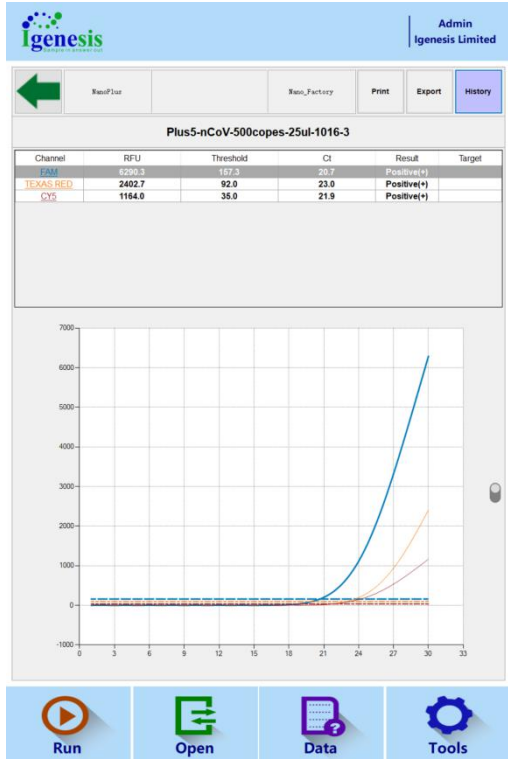


Figure 4-6 Result Interface

Please refer to figure 4-6.1 for the menu of result interface:

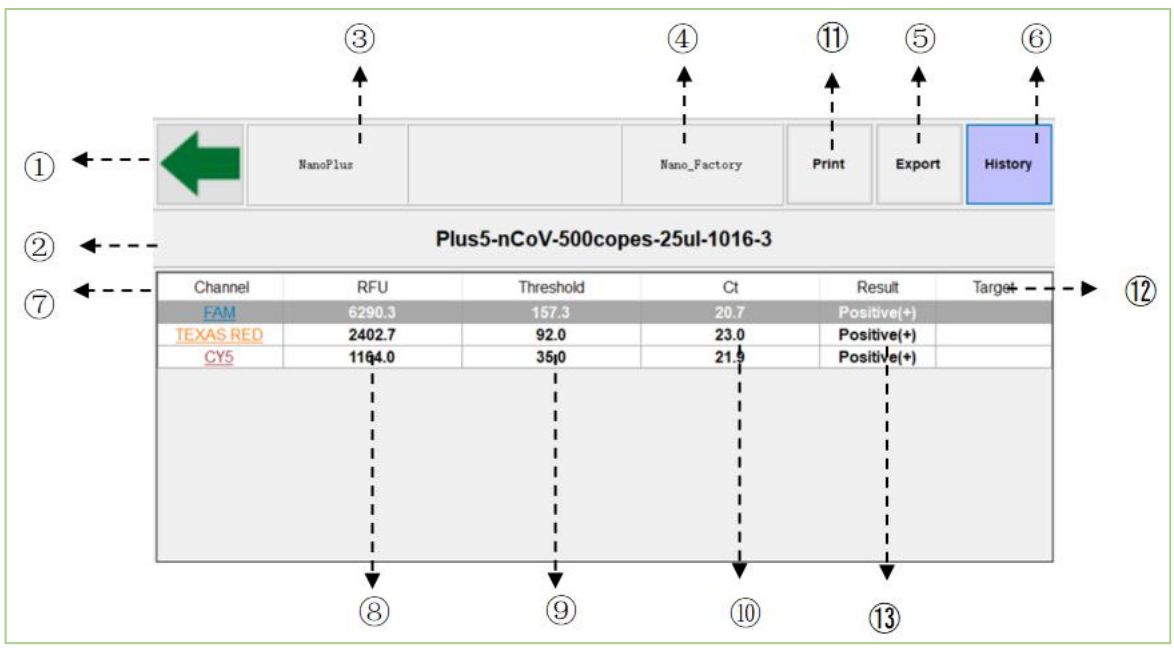


Figure 4-6.1 Result Interface-Menu

1. **Return Key:**

   This key is functioned to switch to running interface or initial interface.

2. **Program Name:**

It is the reagent program name currently running.

3. **Instrument Model:**

   It is the current instrument model.

4. **Username:**

   It is the current username.

5. **Export:**

   It is functioned to export the current experiment data and to save as .txt,.xlsx and .pdf.

6. **History:**

   It is the historical results. Users can double click on a historical result to view details of PCR.

7. **Channel:**

   It is channel name list.

8. **RFU:**

   It is the fluorescence signal value after PCR amplification is completed.

9. **Threshold:**

   It is the fluorescence threshold value, a fluorescence intensity standard set during the growth period of fluorescence amplification curve. Double click the fluorescence threshold to change it if needed.

10. **Ct:**

    It is the number of amplification cycles when amplification product reaches the threshold during PCR amplification.

11. **Print:**

    It is functioned to print the current test report.

12. **Target:**

    It is the gene segment.

13. **Result:**

    It is the qualitative result which determines that the to-be-tested sample is negative or positive via calculating Ct value.

Please refer to figure 4-6.2 for the amplification curve of result interface:

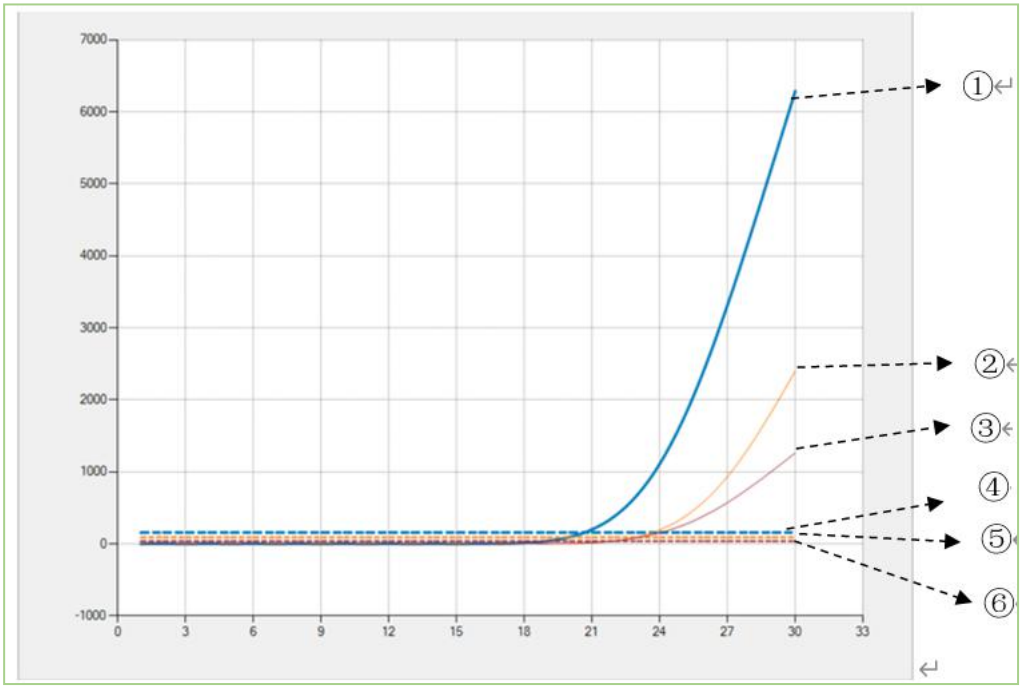


Figure 4-6.2 Result Interface-Amplification Curve

1. **Amplification Curve:**

   It is the amplification curve of channel FAM.

2. **Amplification Curve:**

   It is the amplification curve of channel TEXAS RED.

3. **Amplification Curve:**

   It is the amplification curve of channel CY5.

4. **Fluorescence Threshold:**

   It is the FAM threshold in channel FAM.

5. **Fluorescence Threshold:**

   It is the TEXAS RED threshold in channel TEXAS RED.

6. **Fluorescence Threshold:**

   It is the CY5 threshold in channel CY5.

4.2.10 End of Operation

Users need to pull out the single-use iCassette from the ejected sample tray and throw it into medical dustbin after procedure is completed.

Bio-hazard: Used iCassette shall be disposed by trained professionals only.

When processes the toxic, corrosive or infectious samples, users must follow relevant local safety regulations. The used iCassette must not be thrown into public dustbin but medical dustbin.

The user can then load a new iccassete as described in 4.2.4 to start test, or click the "Close" button to inject the sample tray and shutdown the instrument.

4.3 Instrument Shutdown

Press the instrument switch in front of Galaxy Nano over 5 seconds till the blue indicator light on front panel is off. Then the instrument is shut down.

Warning: Please do not touch the tray when the Sample Room is opening and closing, otherwise hand injury may be caused.

Warning: Please do not unplug the instrument before the blue indicator light is off, otherwise system breakdown and data loss may occur.

Warning: Please ensure there is no iCassette left in the cabin before turning off the instrument, otherwise the instrument may be damaged during the next self-checking.

Users need to unplug the power cable after Galaxy Nano instrument is turned off.

Warning: If Galaxy Nano instrument is turned off but is not unplugged, the instrument will stay in power standby mode and continue to consume power.

4.4 Other Operations

- **Stop:**

  After users click **Run** and before Galaxy Nano instrument finishes processing, **Run** will change to **Stop**. Users can click **Stop** to terminate current process. When a process is terminated, the hardware of Galaxy Nano instrument will be reset. The reset time may be different. The system will return to initial interface after reset.

  Warning: If a process is terminated, Galaxy Nano instrument will not save any data and the iCassette cannot be reused. Please dispose iCassette as a waste according to Part 6.4. so users shall estimate the risks before stopping the processing.

- **Sample Room Open and Close**:

When Galaxy Nano instrument is not processing any sample, click **Open/Close** in the menu bar to open or close the sample room door.

Waring Hands Pinching: Do not touch the tray by hand while the sample room is opening and closing, otherwise hands injury will be caused.

- **View History Report**:
  - User could click **Data** in menu bar, as shown in figure 4-7.

Figure 4-7 Data in Menu Bar

  - Then click **History** in data interface and the list of all historical reports are displayed. User could select and double click any report he or she wants to view, as shown in figure 4-8.

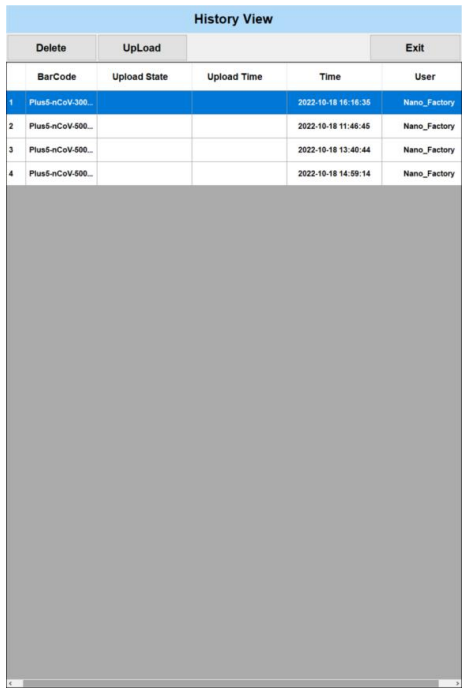


Figure 4-8 History Report

4.5 Purchase of Reagent Program

Galaxy Nano instrument can just process reagents with built-in processing program. Click **Run** and the instrument will select an appropriate processing program according to the QR code. If the reagent processing program is not found, the instrument will not process the iCassette.

If users need to purchase a new reagent program from Igenesis, please contact sales personnel of Igenesis for details and contact after-sales service for adding new reagent program.

Please add the new reagent program according to the following steps:

- Click **Tools** to enter tools interface, as shown in figure 4-9. then click **Program Management** to enter program management interface, as shown in figure 4-10.

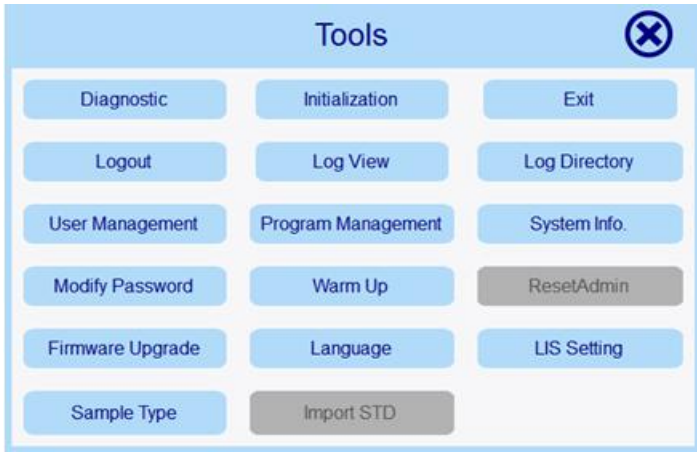


Figure 4-9 Tools Interface

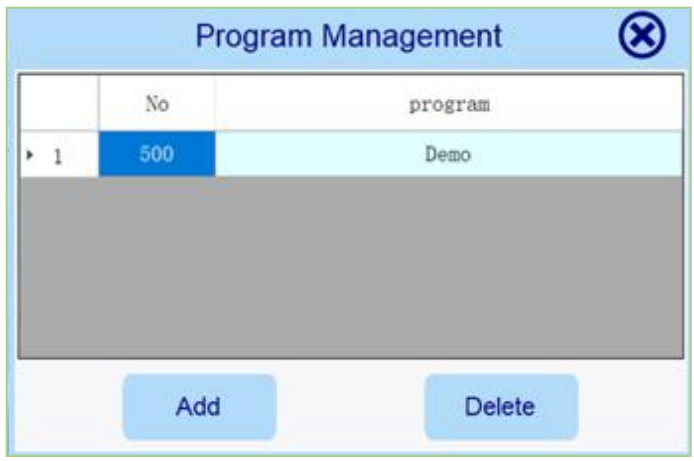


Figure 4-10 Program Management Interface

- Click **Add** to enter the new reagent program adding window, select the new reagent programme as shown in figure 4-11.

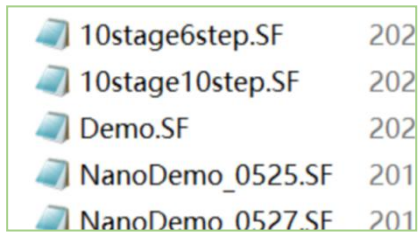


Figure 4-11 Add New Reagent Program

- After the regent program is added, the No. and program name will be displayed.
- Please update the added reagent program and close program management window.

5. Software Function and Characteristic

5.1 Overview

This section introduces Galaxy Nano system software functions and characteristics.

5.2 login

Please double click “Nano. exe” to enter the system software login interface, as shown in figure 5-1.

Figure 5-1 Login Interface

Please enter the username and password to click **login** to log in the system software. If the input box is empty, the system will prompt that “The username shall not be empty.” Or “The password shall not be empty”. If input the wrong username or password, it show “The username or password is incorrect.” and empty the password.

5.3 Run

The running interface displays the remaining time, running progress and iCassette status after starting running.

Please refer to Part 4.2.7 for **Run** key details and Part 4.4 for **Stop** key details.

5.4 Sample Room Open and Close

The sample room door of Galaxy Nano is able to open and close automatically, and the instrument will be initialized.

5.5 Data

Galaxy Nano is capable of searching experiment results which can be saved as .txt. Please refer to **View History Report** in Part 4.4.

5.6 Tools

User could click **Tools** to enter tools interface, as shown in figure 5-2. The tools interface is composed of **Diagnostic**, **Initialization**, **Exit**, **Logout**, **Log View**, **Log Directory**, **User Management**, **Program Management**, **System Info.**, **Modify Password**, **Warm Up**, **Reset Admin**, **Firmware Upgrade**, **Language**, **Lis Setting** and **Sample Type**.

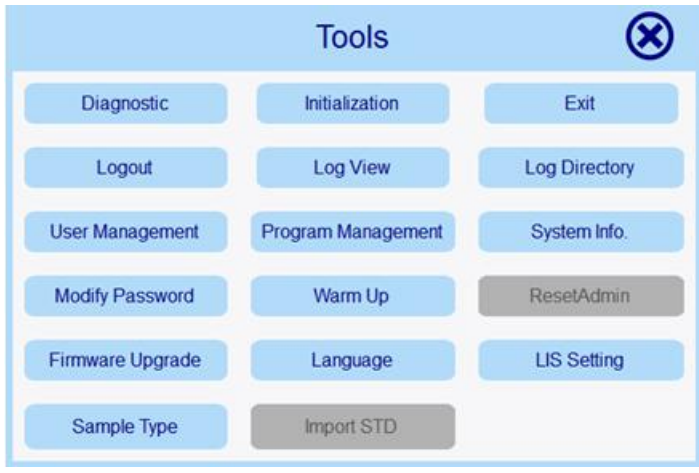


Figure 5-2 Tools Interface

5.6.1 User Management

User could click **user management** to enter its interface, as shown in figure 5-3. The left part is the existed users while the right part is the function of **Add** and **Delete**.

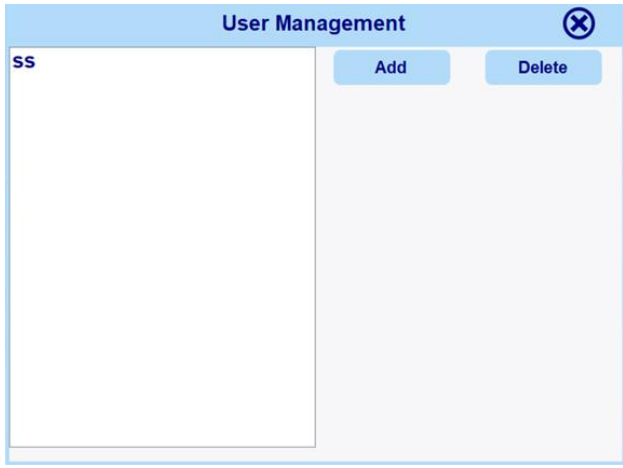


Figure 5-3 User Management

- **Add**:

  User could click **Add** to add a user, as shown in figure 5-4. Please pay attention to that the user shall not be empty, Admin, Nano Factory and not be same to the existed user. After entering the username and password, please click **OK** to finish user addition and the user will be shown in left part, as shown in figure 5-5.

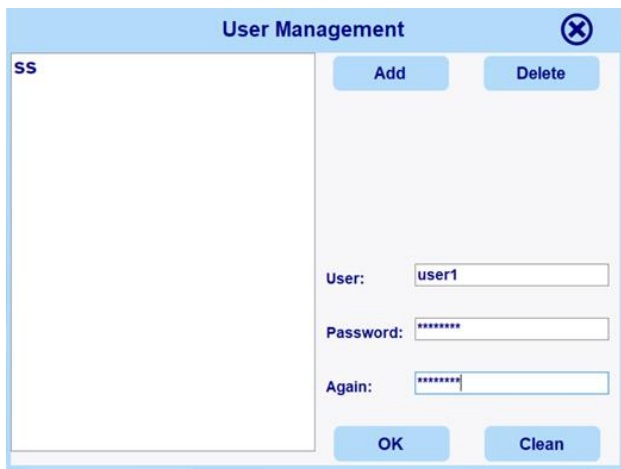


Figure 5-4 Add User

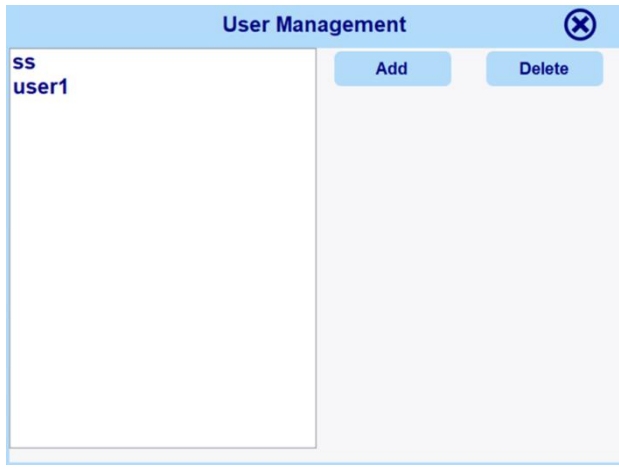


Figure 5-5 Added User

- **Delete**:

  User could select a user and click **Delete** to delete it, as shown in figure 5-6.

Figure 5-6 Delete User

- **Modify Password**:

  User could click on **Modify Password** in **Tools** to enter password modification interface, as shown in figure 5-7.

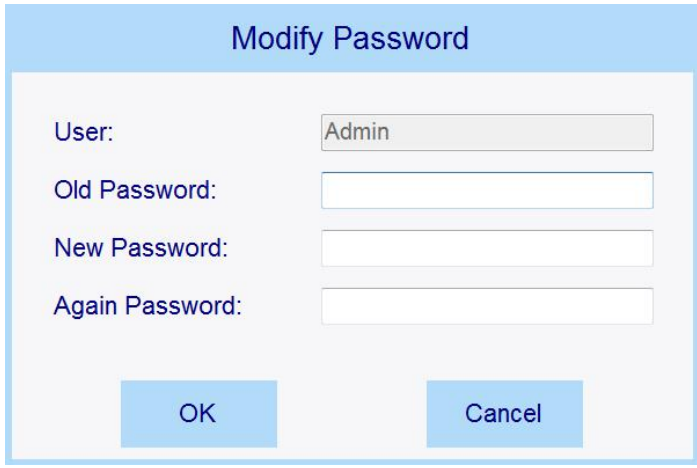


Figure 5-7 Modify Password

- **Username**: It is the current username that need to modify password.
- **Old Password**: Please enter the old password.
- **New Password**: Please enter a new password including number, letter and special character, with 6-20 characters.
- **Again Password**: Please enter the new password again.
- **OK**: The password is successfully changed, and the user information document should be updated at the same time.
- **Cancel**: This is to abandon password modification.

5.6.2 Initialization

- This function needs administrator authorization and the instrument is idle.
- Please conduct instrument initialization.

5.6.3 Exit

- Exit and close the software.
- Exit the system software is only when the system is idle..

5.6.4 Logout

- Exit the current user account.
- Please click **Logout** to log out the system software when the instrument is not running any program.

5.6.5 Log View

- User could click **Log View** to check the operation records, including user login, logout, sample room open/close, initialization, reagent program name, iCassette QR code, etc.

5.6.6 Log Directory

- **Log Directory**: Please open the folder that stores data log with the admin authorization, as shown in figure 5-8.

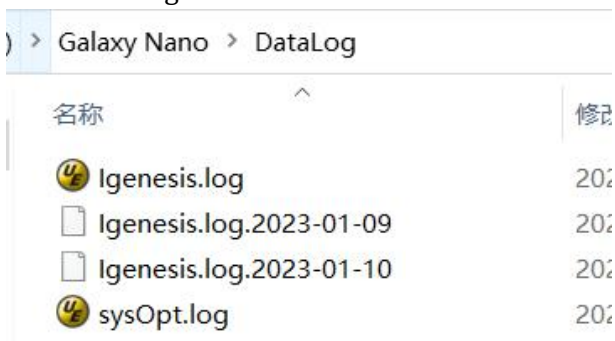


Figure 5-8 Log Directory Window

5.6.7 Program Management

- This operation needs the admin authorization and the program management window as as shown in figure 5-9.
- **No.**: It is the program code that is hexadecimal and cannot be reused.
- **Program:** This is the file name of program which can be reused.
- **Add:** Add a new program from a specified path, and the system will copy the program

to the installation path.

- **Delete**: This is for deleting the selected program file.
- The correspondence of QR code and program will be saved in the software configuration file. The system could maximally support 1024 programs and errors will be reported if the quantity is over 1024.

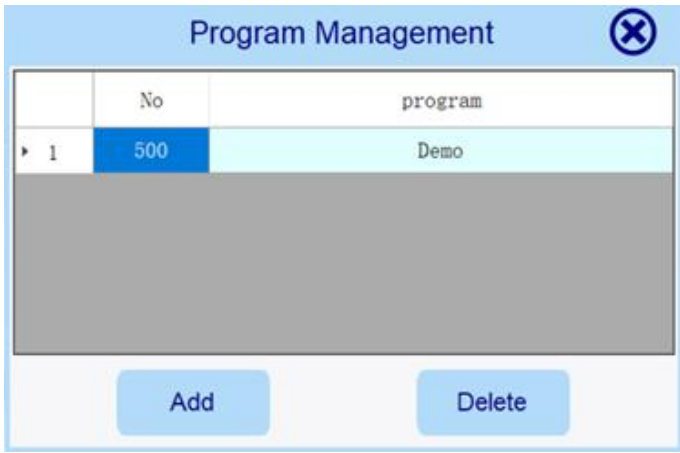


Figure 5-9 Program Management Window

5.6.8 System Information

User could click **system information** to check Galaxy Nano instrument's serial number and version information.

5.6.9 Language

User could set Galaxy Nano system software language here by clicking **Language** to switch the language into **Chinese** or **English**.

5.6.10 Reset Admin

Only the authorization of factory user could conduct the reset function with admin password.

5.6.11 Warm Up

User could click **warm up** to Warm Up the instrument for 30 minutes when turns on the instrument at the first time.

5.6.12 Diagnostic

If the color is gray, the instrument is not connected, and if it is green, the instrument is connected. It needs admin authorization to enter the diagnostic interface when the instrument is idle, as shown in figure 5-10.

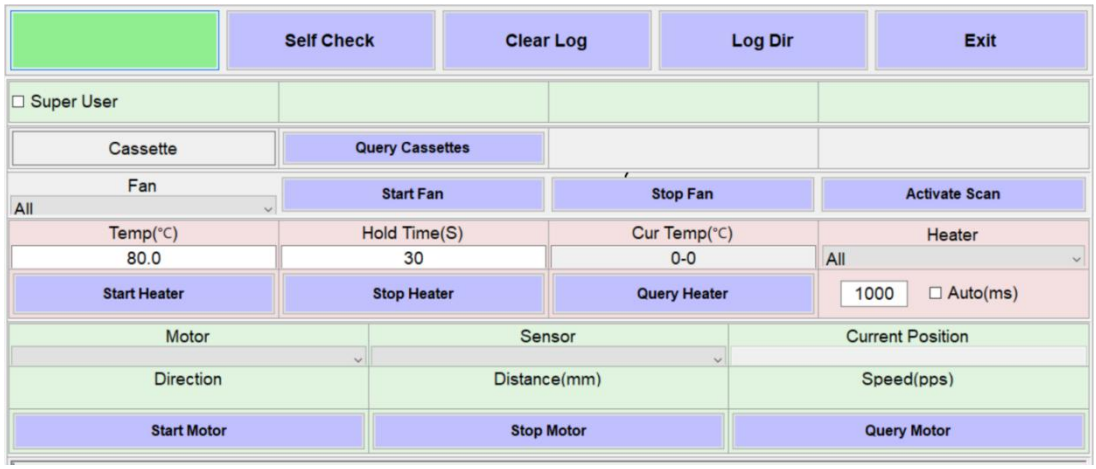


Figure 5-10 Diagnostic

- **Self-Check:** Please refer to Part 5.6.11.1 for self-check operation.
- **Clear Log**: This key is for clearing the diagnostic information.
- **Log Dir:** This is the folder that stores the diagnostic information.
- **Exit**: This key is to exit the diagnostic interface.
- **Super User**: The super user authorization could make the motor to neglect the rules.
- **Query iCassettes**: This is for checking if there is a icassette in the instrument by a icassette sensor.
- **iCassette**: This is the icassette status. When click **Query iCassette**, if icassette is existed, the i**Cassette** background is green. If not, the background color will not be changed.
- **Fan**: This is a switch to control the left, right and PCR.

- **Start Fan:** This is for starting the fan.
- **Stop Fan:** This is for stopping the fan.
- **Activate Scan:** This is for controlling QR code scanning engine to read QR code.
- **Temp(℃):** This is for setting temperature of Heater from 50-140℃.
- **Hold Time(S):** This is for setting the constant temperature time of Heater.
- **Cur Temp(℃):** This is the current temperature of the Heater.
- **Heater**: This is for selecting the heating channel in the drop-down box.
- **Start Heater:** This is for starting the function of heating.
- **Stop Heater:** This is for stopping the function of heating.
- **Query Heater**: This is for checking the temperature value of **Heater**.
- **Motor:** This is for selecting the current motor ID from All and 1-9.
- **Sensor:** This is for selecting the sensor location from Origin, 1-12, Limit (Motor sensor can be set in factory version software). If the sensor is not selected, motor will move by distance.
- **Current Position**: This is the motor's current position.
- **Direction:** This is the motor moving direction (forward, back).
- **Distance(mm)**: This is the motor's moving distance.
- **Speed(pps)**: This is the motor's moving speed, with the range of 500-16000.
- **Start Motor:** This is for starting the motor.
- **Stop Motor:** This is for stopping the motor.
- **Query Motor:** This is for checking the motor status.

5.6.12.1 Self Check

User could click **Self Check** go enter its interface , as shown in figure 5-11.

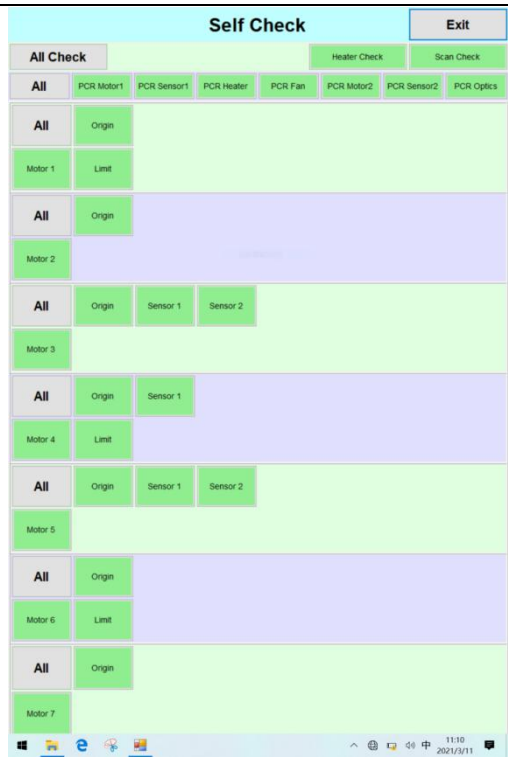


Figure 5-11 Self Check Interface

- **Exit:** This is to exit the self check interface. If the system is performing self checking, the exit function cannot be realized.
- **All Check**: All check is composed of Heater, Motor, Scan and PCR module. After self check, all motors move to the original position except the motor of the door.
- **Heater Check**: This is the self check of heater module.
- **Scan Check**: This is the self check of QR code scanning engine.
- **PCR Motor**: This is the self check of PCR runner motor.
- **PCR Sensor**: This is the self check of PCR sensor.
- **PCR Heater**: This is the self check of PCR heating module.
- **PCR Fan**: This is the self check of PCR fan.
- **Motor***: This is the self check of the single motor.

- **Origin, Sensor1-Sensor12, Limit:** This is the self check of the single sensor. Blank means no sensor. For sensor setting, please refer to the factory version software specifications.
  - For a single self check, red indicates an error; Green indicates uncovered; Yellow indicates covered; Gray indicates unknown or self check failure.
  - For all self check, red indicates an error; Green indicates uncovered; Yellow indicates covered; Gray indicates unknown or self check failure.

5.6.13 LIS Setting

User could add the master computer IP address to upload the data to LIS system.

5.7 Data Port

The data port consists of physical port, USB Type C port, transmission protocol and private protocol. These are for data communication between system software and instrument.

5.8 User Visit

Galaxy Nano use username and password to identify the user. The system software user is composed of factory user, admin and common user. The factory user could operate all the functions of the instrument. The admin could enjoy all the functions except **Reset Admin** function. The common user could operate **Start**, **Stop**, **Sample Room Open &Close**, **Data** and the functions in **Tools** like **Exit**, **Logout**, **Log View**, **System Info.**, **Warm Up** and **Language**.

5.9 Software Characteristic

5.9.1 Compatibility

The system software shall run in Windows 10 Home, 64-bite or its compatible operation system. It is only used for Galaxy Nano instrument. Before running it, user shall configure the running environment according to the **Application Conditions** in Part 2.6.

5.9.2 Usability

Galaxy Nano system software user port type is menu, window and function keys. The operator who uses the instrument shall know about the bio-medical knowledge. The system software does not own the copyright protection. When user deletes the history data, user account, reagent program of the system software, it will prompt user whether to delete it.

5.9.3 Reliability

If the master computer, pad or PC is confronted with an unexpected power-off during system software running, it can be recovered to the normal running after troubleshooting and reboot.
User shall duplicate the PcrData by him or herself to avoid the unexpectedness. The backup steps are as follows:

- **Data Backup**: Please open Galaxy Nano system software installation package, select PcrData folder and paste it to the path where user needs to store backup data.
- **Data Recovery**: Please find PcrData file in the path that user stores backup data and paste it to PcrData folder of the Galaxy Nano software.

5.9.4 Information Safety

Galaxy Nano software identifies the user with username and password. It supports different levels users. The system software's confidential data is PcrData and it adopts the precise MD5 tamper-proofing algorithm to ensure the stored data integrity.
The Galaxy Nano system software has a user operation log that records the user's login, logout, open/close, initialisation, operation stop, exit, data management actions, program management actions, user management actions, and the name of the reagent program run by the user, the two-dimensional code of the kit, the communication connection status, and the operation completion status.
The different data managed by user corresponds to the software information safety levels are as follows:

Data	Safety Level
User Password (could change or delete)	low
Username (could change or delete)	low
Reagent Program (could change or delete)	low

5.9.5 Maintainability

Galaxy Nano system software log records the errors occurred during running so as to identify and solve the errors by after-sale personnel.

Note: The system software shall not be modified by user.

5.9.6 Software Portability

The system software could run normally under the configurations in 2.6 section. It is a free-installation software. If user wants to remove it, please select Galaxy Nano installation package and delete it.

6. Instrument Cleaning and Maintenance

6.1 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 power module.

b. Wipe the surface of the instrument thoroughly with a lint free cloth and wait for 10 minutes;

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**: Turn off the instrument and unplug the power cable before cleaning the instrument.

⚠ **Warning**: Do not clean Galaxy Nano instrument with cleansers of strong acid and strong alkali containing sodium hypochlorite, caustic soda, sulfuric acid, hydrochloric acid and etc. Do not use cleansers that will have chemical reactions with internal parts of Galaxy Nano instrument. Please contact after-sales service if user has any question about the cleansers compatibility with Galaxy Nano instrument.

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

6.2 Instrument Protection

Please use the power cable provided by the manufacturer.

⚠ **Warning**: Please do not disassemble the instrument save the professionals trained.

6.3 Waste Disposal

Plenty of amplification products will be left inside the icassette after every processing. In order to avoid contamination of laboratory and instrument, user should dispose the icassette following the laboratory rules. The used icassette should be discarded into medical waste bins instead of public dustbins.

Bio-hazard: Please do not open the used icassette, otherwise the laboratory will be contaminated by the high concentration nucleic acid.

Bio-hazard: The used icassette or waste must be disposed by professionals trained.

6.4 Maintenance

User shall calibrate the instrument regularly to ensure a good perform for the instrument. It is recommend to calibrate the instrument every 12 months. User could contact after-sales service or the qualified institution for instrument calibration.

Please contact after-sale service for the every 6-month maintenance.

Please contact after-sale service for system software upgrade.

Please contact after-sale service for purchasing if the adapter is damaged.

Please contact after-sale service for the best disposal if the instrument reaches the valid period.

Appendix 1 Troubleshooting

Problem	Cause	Solutions
Ⅰ. Sample tray is stuck after loading a icassette when clicks **Close**.	1.The iCassette is loaded improperly. 2.The instrument errors occur.	1. Reload the iCassette properly. 2. Contact after-sales service for further support.
Ⅱ. Click **Run** and the system reports an error of "iCassette not found".	1. The iCassette is not loaded. 2. The instrument errors occur.	1. Load a icassette. 2. Contact after-sales service for further support.
Ⅲ. Click **Run** after loading a icassette, and the system reports "iCassette error".	1. QR code of the iCassette is incorrect. 2. The instrument errors occur.	1. Replace a icassette with a QR code that can be identified by the system; 2. Contact after-sales service for further support.
Ⅳ. Click **Run** after loading a icassette, and the system reports "Wrong iCassette ".	1. It is a wrong type of icassette that cannot be used for the system.	1. Use the icassette that can be run by the system.
Ⅴ. The motor does not move to the position of the selected sensor".	1. The position sensor is covered by dust and other tiny objects. 2. The instrument errors occur.	1. Cut off the power and restart instrument; 2. Contact after-sales service for further support.
Ⅵ. X motor errors.	1. The position sensor is covered by dust and other tiny objects. 2. The instrument errors occur.	1. Cut off the power and restart instrument; 2. Contact after-sales service for further support.
Ⅶ. XX sensor error.	1. The position sensor is covered by dust and other tiny objects. 2. The instrument errors occur.	1. Cut off the power and restart instrument; 2. Contact after-sales service for further support.
Ⅷ. Heating module error.	1. The instrument errors occur.	1. Contact after-sales service for further support.
Ⅸ. Heating of PCR module error.	1. The instrument errors occur.	1. Contact after-sales service for further support.

Appendix 2 Test Method of Over-temperature Protection Device

- **Purpose:** To ensure that the over-temperature could run normally.
- **Test Cycle: 1 time/year**

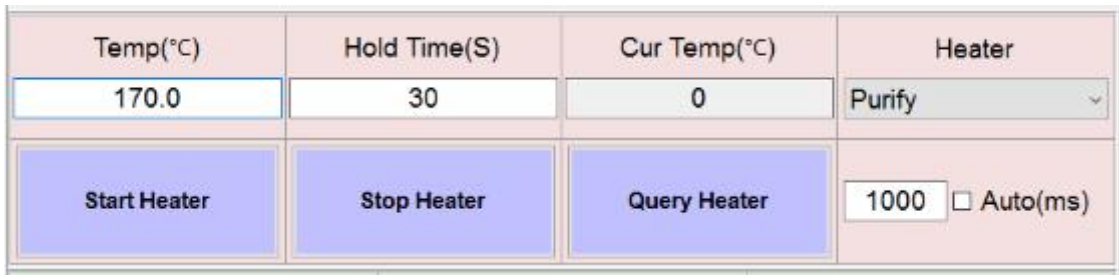
  Note: Test of over-temperature may affect performance of Galaxy Nano instrument. If unnecessary, repeated or multiple test is not recommended.

- **Test Steps:**

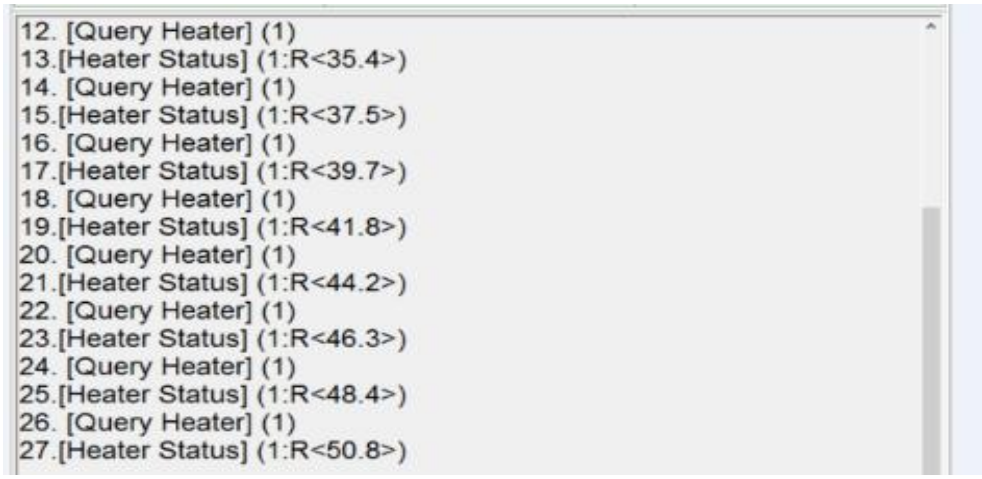
1. Log in system with the account of administrator.
2. Click **Tools→Diagnostic** after logging in the system.
3. Test the temperature protection device for extraction heating.

① Select **Diagnostic → Heater → Purify** in the drop-down menu.

② Set "Temp (℃)" as 170℃ and "Hold Time (s)" as 30s.



③ Check "Auto(ms)" to print temperature of the heating tip in every second.



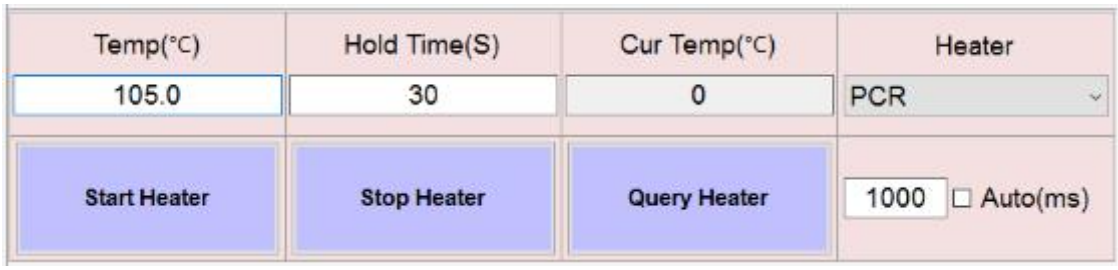
④ Observe the temperature data printed in real time. If it reaches 120℃±5℃ (lower than 170℃) and falls suddenly at a point, the extraction heating device will be turned into the protection status. Then restart Galaxy Nano instrument to reset it.

⑤ If the temperature data printed in real time reaches 170℃ and even higher, the heating protection device doesn't work, users must contact the after-sales service for maintenance.

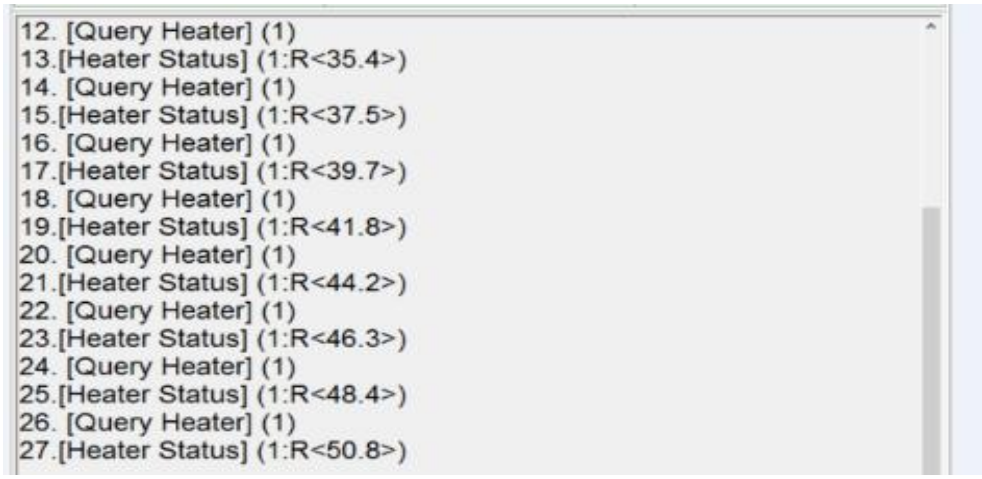
4. Test the temperature protection device for PCR heating.

① Select **Diagnostic →Heater** in drop-down menu **→PCR**.

② Set "Temp(℃)" as 110℃ and "Hold Time (s)" as 20s.



③ Check "Auto(ms)" to print temperature of the heating device in real time in every second.



④ Observe the temperature data printed in real time. If it reaches 105℃ (lower than 110℃) and falls at a point, PCR heating device will be turn into protection status. Then restart Galaxy Nano instrument to reset it.

⑤ If the temperature data printed in real time reaches 110℃ and above, and the heating protection device doesn't work, users must contact the after-sales service for maintenance.