

BIOBASE[®]

**Automatic Nucleic Acid Extraction System
BK-HS32
User Manual**

BIOBASE GROUP

Version 2020.09

Preface

Thank you for purchasing Automatic Nucleic acid extraction system (BK-HS32).

Before using the instrument, please read the contents of this operation manual carefully to ensure proper operation.

Please keep this manual well for reference when needed.

Product name: Automatic Nucleic acid extraction system

Model: BK-HS32

Scope of application: Used for the extraction and purification of nucleic acids in clinical samples.

Registrant/Manufacturer: Biobase Biodustry(Shandong) Co., Ltd.

Intellectual property

The intellectual property rights of this operation manual and its corresponding instrument belong to Biobase Biodustry(Shandong) Co., Ltd.

Without the written consent of Biobase Biodustry(Shandong) Co., Ltd. no individual or organization may copy, modify or translate any part of this manual.

Statements

The contents of this operation manual are consistent with the situation of this product.

Biobase Biodustry(Shandong) Co., Ltd. reserves the final right to interpret this operation manual.

Biobase Biodustry(Shandong) Co., Ltd. assumes responsibility for the safety and reliability of the product only if it meets all of the following requirements:

- Assembly, commissioning and maintenance of the instrument are performed by Biobase Biodustry(Shandong) Co., Ltd. after-sales service engineers or other authorized professionals by Biobase Biodustry(Shandong) Co., Ltd.;
- All the parts and consumables used for replacement and maintenance are provided or accepted by Biobase Biodustry(Shandong) Co., Ltd.;
- Relevant electrical equipment complies with national standards and the requirements of this operation manual;
- The operation of this instrument is in accordance with this operation manual.

After-sales service

The standard warranty period of this product is 1 year. Within this warranty period, the products are entitled to receive free after-sales service; however, the product needs to be repaired due to the following reasons, which does not fall into the free after-sales range. You need to pay for maintenance and accessories:

- Improper use and man-made damage.
- Grid voltage or electromagnetic interference does not conform to the product specified range.
- Irresistible natural disasters.
- Replace or use non-Biobase Biodustry(Shandong) Co., Ltd. original (original) or non-Biobase Biodustry(Shandong) Co., Ltd. approved parts, accessories, consumables or repaired by non-Biobase Biodustry(Shandong) Co., Ltd. authorized personnel.
- After the warranty period expires, Biobase Biodustry(Shandong) Co., Ltd. can continue to provide repair services for fees.
- Disassemble the instrument by yourself.
- Failures caused by other than the product itself.

User qualification

This system should only be operated by professionals, doctors, or experimenters trained by Biobase Biodustry (Shandong) Co., Ltd. or agents of Biobase Biodustry (Shandong) Co., Ltd., and the operator must be systematically trained in Automatic Nucleic acid extraction system (BK-HS32) to meet the corresponding requirements, and have the following qualifications:

- You must have read and understood this operation manual.
- You must know computer operation to a certain level, and have a good command of the instrument and software system operation .
- You must be familiar with corresponding laboratory requirements and local laws and regulations.

Warning:

Personnel without professional training are forbidden to operate this instrument.

About

This manual provides description about main structure, function, performance, installation, use, operation, maintenance, repair, storage and safety precautions to protect the operator and the instrument related with the BK-HS32, please see the corresponding chapter for details. Before using this instrument, users should read this manual carefully for better understanding and command of the operation knowledge.

Note:

The readers of this Operation Manual are the following professionals:

- daily operation personnel;
- Maintenance and troubleshooting personnel;
- People who learn to operate.

The "extractors, instruments, and systems" mentioned in this article all refer to "BK-HS32 Automatic Nucleic acid extraction system".

Content

Preface.....	1
1.Foreword.....	6
1.1 Symbols.....	6
1.2 Security precautions.....	7
1.2.1 Work environment requirements.....	7
1.2.2 Electricity safety.....	8
1.2.3 Electrical danger.....	9
1.2.4 Mechanical danger.....	9
1.2.5 Electromagnetic interference prevention.....	9
1.2.6 Biological risk protection.....	10
1.2.7 Other precautions.....	10
1.3 Accessories list.....	10
1.4 Consumable service life.....	10
2. Module function introduction.....	11
2.1 Performance parameters.....	11
2.2 Module structure and function.....	12
2.2.1 Structure of magnetic rod and rod sleeve.....	12
2.2.2 Function of plate positions.....	12
2.2.3 Function of floodlight.....	12
2.2.4 Function of HEPA.....	13
3.Operation guidance.....	15
3.1 Boot.....	15
3.2 Program running.....	15
3.2.1 Program viewing.....	16
3.2.2 Program running.....	16
3.2.3 Alarming.....	17
3.3 Program management.....	18
3.3.1 Add.....	19

3.3.2 Edit.....	20
3.3.3 System default program.....	21
3.4 Program management.....	22
3.4.1 Language settings.....	23
3.4.2 Instrument Debug.....	23
3.4.3 Import/Export.....	23
3.4.4 Software upgrade.....	23
3.5 UV disinfection.....	24
3.6 About.....	25
3.7 Exit.....	26
4.Maintenance.....	27

1.Foreword

1.1 Symbols

You may see these signs, labels and symbols used with text on the BK-HS32 to remind operators of the warnings and potential dangers, please understand the meaning of the symbols before use.

Symbols	Description
	<p>Biological risk:</p> <p>This mark appears on the instrument as a warning of the risk of contamination associated with biological or chemical materials.</p>
	<p>Heat warning label.</p> <p>When this mark appears on the instrument, it is a warning for high temperature parts, be careful of hot hands.</p>
	<p>Anti-squeeze sign.</p> <p>When this mark appears on the instrument, it is a warning for moving parts. Be careful of squeezing hands.</p>
	<p>Safety warning label.</p> <p>When this mark appears on the instrument, attention should be paid to safety to prevent collision or entrapment!</p>
	<p>Fuse specification label.</p>
	<p>Interface and switch identification on the rear of the instrument.</p>
	<p>The company logo.</p>

Text description in the manual.

Text	Description
Notice	Used to illustrate important information in the action steps or other things that need to be brought to the user's attention.
Warning	Remind the user to follow the instructions, otherwise it may result in personal injury.

1.2 Security precautions

In order to use the system safely and effectively, please read the following safety precautions carefully. Any operation that violates the following safety precautions may result in system damage or personal injury. If operating the instrument without following the instructions, the protective measures provided by the system may fail.

1.2.1 Work environment requirements

Considering the safety and performance of the instrument, the environment in which the Automatic Nucleic acid extraction system is installed and the working environment of the instrument shall satisfy the following scientific conditions:

- environmental temperature: 10°C~40°C.
 - Relative humidity: ≤80%.
 - Atmospheric pressure: 76kPa~106.0kPa.
 - No strong magnetic field interference and mechanical vibration, no corrosive gas.
 - With the surrounding walls or other electrical equipment to keep a distance of 50 cm or more.
 - The power supply AC 220V 50HZ
 - only applies elevation 2000 meters below the safe use
-

1.2.2 Electricity safety

In order to use electricity safely and prevent electric shock and damage to the instrument, please observe the following precautions.

Warning:

- This instrument is only suitable for non-domestic use and cannot be directly connected to the residential low-voltage power supply network.
 - If there are external switches or fuses or protection devices for over current , these switches or circuit breakers should be installed near the equipment.
 - Do not place the instrument where it is difficult to operate the disconnection device. If the plug of the power supply cannot be disconnected immediately in an emergency, make sure that the wall socket connected to the instrument's power supply can be touched by hand at all times.
 - After the installation is completed, customers are not allowed to move the instrument without authorization. If the instrument must be moved, please contact the installation engineer for on-site service.
 - This system is connected to the ground via ground wire. The power ground wire must be grounded to avoid electric shock.
 - The AC power supply must be stable. It is forbidden to share the power supply with high-power appliances.
 - When the user runs or maintains the instrument, do not touch the power connector on the back of the system, otherwise there may be danger of electric shock.
 - When the main power of the instrument is turned on, non-authorized maintenance personnel must not disassemble the cover of the instrument.
 - Spilling the solution into the instrument may cause the instrument to malfunction and cause electric shock. Do not place objects on the instrument. In the event of a spill, immediately turn off the power and contact Biobase Biodustry(Shandong) Co., Ltd. Customer Service or your local service representative.
 - Do not plug or unplug the power supply with wet hands.
 - Disconnect it from all power sources before opening the instrument for any maintenance or repair which should only be performed by a person who is skilled and understands the hazards.
 - Make sure that the replaced power supply meets the requirements
-

of this instrument.

- If the instrument may be damaged, disconnect it from the power outlet and do not operate it again.
-

1.2.3 Electrical danger

To prevent electrical hazards, please observe the following precautions.

Warning:

- The operator must always observe the electrical safety operation regulations. Only professional personnel can perform electrical repairs. Please wear static-free wrist straps or gloves during maintenance to protect the sensitive components on the instrument from electrostatic damage.
-

1.2.4 Mechanical danger

To prevent mechanical hazards, please observe the following precautions.

Warning:

- The moving parts of the system may cause injury to personnel during operation. During the experiment, the door of the instrument compartment must be closed. It is strictly prohibited to extend body parts into the working area of the machine, otherwise it may cause injury to operators and damage to the instrument.
-

1.2.5 Electromagnetic interference prevention

To prevent electromagnetic interference, please observe the following precautions.

Warning:

- In order to ensure the normal operation, the user has the responsibility to ensure that the instrument operates in an environment of electromagnetic compatibility
 - Electromagnetic interference may affect the normal operation of the device. Do not install the device in an environment with strong electromagnetic field interference.
 - Do not use other medical devices that may generate electromagnetic interference around the instrument, otherwise it may affect the normal operation of the instrument.
-

1.2.6 Biological risk protection

To prevent biohazard effectively, please observe the following precautions.

Biological risk:

- All liquids and solids in the laboratory are considered to be biological hazards and the user must take general laboratory precautions.
 - All clinical samples are considered to be potentially infectious. Improper use may result in infection. Do not touch the samples directly with your hands. Always wear gloves and overalls to prevent infection during operation. Wear protective glasses when necessary.
 - If the sample accidentally comes into contact with the skin, please immediately follow the work standards for users to handle it and consult a doctor.
-

1.2.7 Other precautions

To use the instrument correctly, please observe the following precautions:

Warning:

- Do not smoke or eat near the instrument.
 - Avoid direct sunlight when the instrument is in operation..
 - Please use the software installation package provided by our company when install the user software
 - During user software start-up or running, it is prohibited to change the date and time of the host.
 - Do not run other applications while the user software is running
-

1.3 Accessories list

No.	Name	Specifications	Number	Note
1	Fuse	F3AL250V	2	

1.4 Consumable service life

In order to ensure the stability and efficiency of the internal pollution discharge system, it is necessary to replace the consumables in the instrument on time.

Ultraviolet lamp: service life 1000 hours.

HEPA filter: service life 500 hours.

2. Module function introduction

2.1 Performance parameters

No.	function	Technical parameters
1	Applicable specimen types:	Serum, plasma, lymph, allelic fluid, semen, saliva, sputum, alveolar lavage fluid, oral swab, cell culture supernatant or other liquid samples.
2	extraction method	Magnetic Bead Method
3	Sample throughput	32
4	Processing volume	20-1000ul
5	Processing time	15min-60min
6	Magnetic bead recovery	≥98%
7	Purification difference between wells	<3%
8	Magnetic flux	4500Gs, Replaceable parts
9	Temperature control range	From room temperature to 100°C in lysis and
10	Oscillation function	Yes
11	Oscillation mode	Oscillating up and down (1 to 3 is adjustable)
12	Location number	2
13	Heating mode	The heating film
14	Temperature display resolution	0.1°C
15	Sample protection function	Power on self-check, power off protection, high temperature alarm, overtemperature protection
16	Disinfection and clean	UV lamp
17	floodlight	LED
18	Safety door design	The instrument is suspended when the safety door is opened
19	Motor protection	The magnet motor is kept still during operation to extend the service life of the motor and guide rail
20	The operating system	windows
21	Barcode scanning	Optional configuration
22	Item storage capacity	>1000
23	The interface type	USB (Ethernet interface can be optional)
24	Built-in air duct	The level 11 HEPA filter can effectively filter the internal aerosol and prevent cross contamination.
25	IAP function	Yes, firmware can be updated online at any time
26	power supply	AC100-240V 50Hz/60Hz
27	Machine size	450mm*440mm*532mm

2.2 Module structure and function

2.2.1 Structure of magnetic rod and rod sleeve

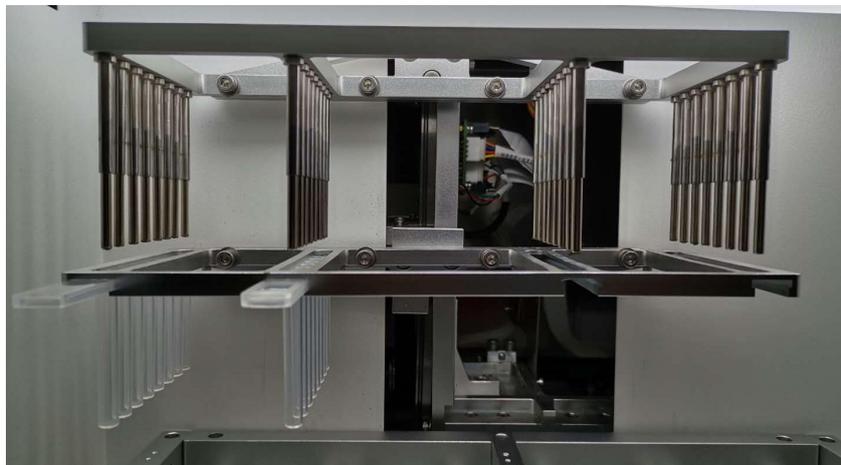


Figure 3-1

The magnetic rod module and the rod sleeve module are independent and independently controlled by the dual Z-axis motors. The rod sleeve module can run independently during the shake and lysis process, and the magnetic rod module and the rod sleeve module also can run as a whole during adsorption process. The motors do not interfere with each other during running.

2.2.2 Function of plate positions



Figure 3-2

There are two positions in the instrument where you can put the deep hole plate, a total of 24 columns of hole positions, of which:

Columns 1-8 identified in Figure 3-2 (the actual hole positions are columns 1, 6, 7, 12, 13, 18, 19, 24) are heating modules, and the temperature control range is from room temperature to 100°C.

Four leaf springs are placed on both plate positions to fasten the deep hole plate.

2.2.3 Function of floodlight

This instrument is equipped with LED floodlights to observe the operating conditions in the cabin during running.

Light on/off method: After the instrument is turned on, there is a "Light" button in the upper right corner of the software interface (the position of the button will not be changed in any interface). Click the "Light" button to turning on or turning off the light in any state.

2.2.4 Function of HEPA

This instrument uses the filter without partitions, which is made of fine glass fiber paper and hot melt glue, and is used for air purification under normal temperature, normal pressure and normal humidity. The HEPA filter can filter the aerosol generated when the instrument is heating or shaking and the dust in daily work.

HEPA open/close method: After the instrument is turned on, there is a "Filter" button in the upper right corner of the software interface (the position of the button will not be changed in any interface). Click the "Filter" button to open or close the filter in any state.

3.Operation guidance

3.1 Boot

Turn on the power switch of the automatic nucleic acid extractor, turn on the instrument and perform a system reset. After the reset is successful, it will enter the main menu interface.

The main interface contains 5 sub-menus such as "Run", "Program Manage", "Instrument Manage", "UV Operator", and "About", as shown in Figure 3-1.



Figure 3-1

3.2 Program running

The program running interface contains three function buttons: "Run", "Scan code to run" and "Select". You can view all the programs that have been entered in the list on the left.

Run: Click to select the program to be run, and then click the "Run" button to directly run the selected program.

Scan code to run: Automatically enter the barcode in the identification kit through the external scan code gun, and refer to chapter 3.3.3 for the introduction of System default program.

Select: Click the corresponding program, and then click "Select" to see the details of the selected program.

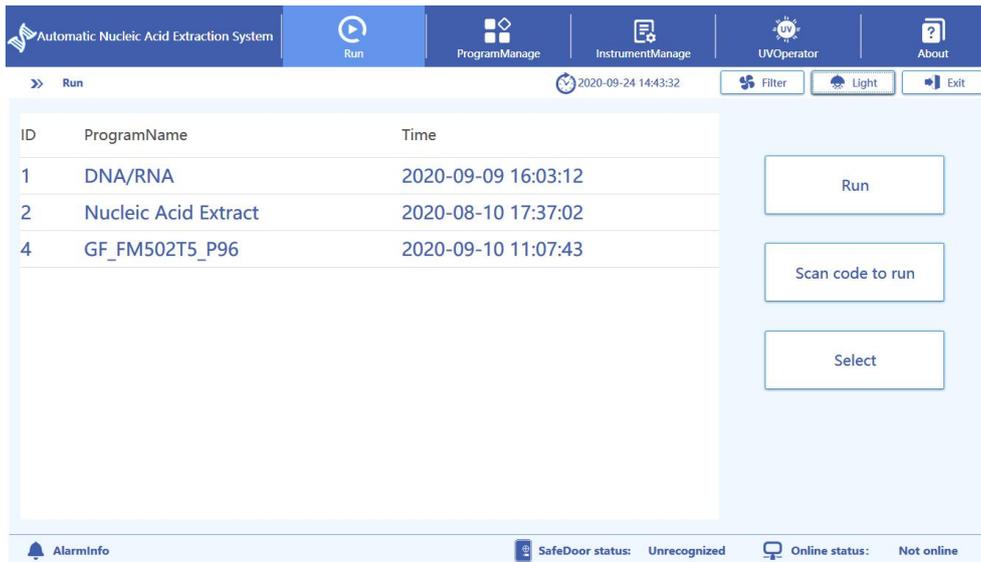


Figure 3-2

3.2.1 Program viewing

Choose a program and click [Select] in the “Run” interface to entering the interface as Figure 3-3, which displays the detailed steps of the program, including the steps name and the time of each step.

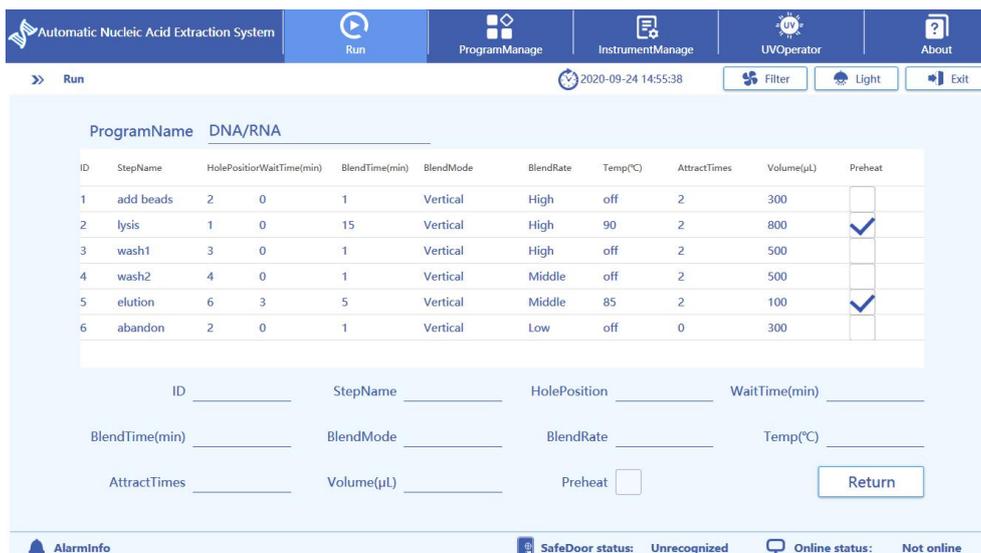


Figure 3-3

3.2.2 Program running

Choose a program and click [Run] in the “Run” interface to running the interface as Figure 3-4.

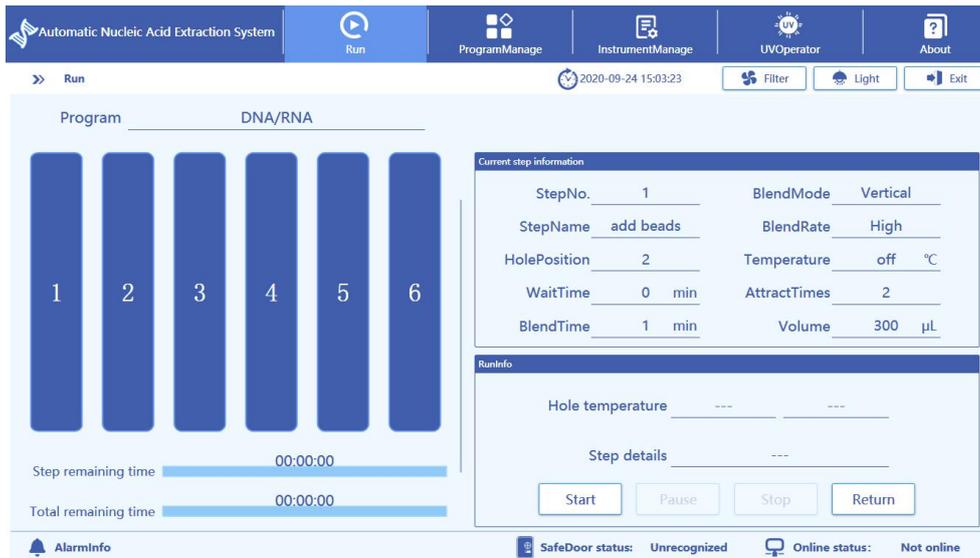


Figure 3-4

After clicking [Start], the program starts to run, [Step Remaining Time] is displayed as the remaining running time of the current step, and [Total Remaining Time] is displayed as the overall remaining running time of the program.

After the program starts running, the [Pause] and [Stop] keys will change from gray to clickable. Click [Pause] to pause the program operation, and the [Pause] button to switch to [Continue], click [Stop], the instrument stops the program operation and automatically resets.

Click [Return] to return to the upper interface.

Note:

1. Do not open the front safety door while the program is running or during the test. If the safety door is opened, the operation will be immediately suspended until the safety door is closed and the running program can continue.
2. When the program is not running, the [Pause] and [Stop] buttons are grayed out.
3. When the program is running, except for the [Pause] button and the [Stop] button, other buttons are grayed out and cannot be operated until the program is finished.
4. When the running program is in the paused state, all buttons except the [Continue] and [Stop] buttons are grayed out and cannot be operated.

3.2.3 Alarming

If abnormal operation or abnormal reset occurs during operation, the instrument will emit a short alarm sound, and at the same time, the alarm information will be displayed after [AlarmInfo] in the lower left corner of the main interface of operation, as shown in Figure 3-5.

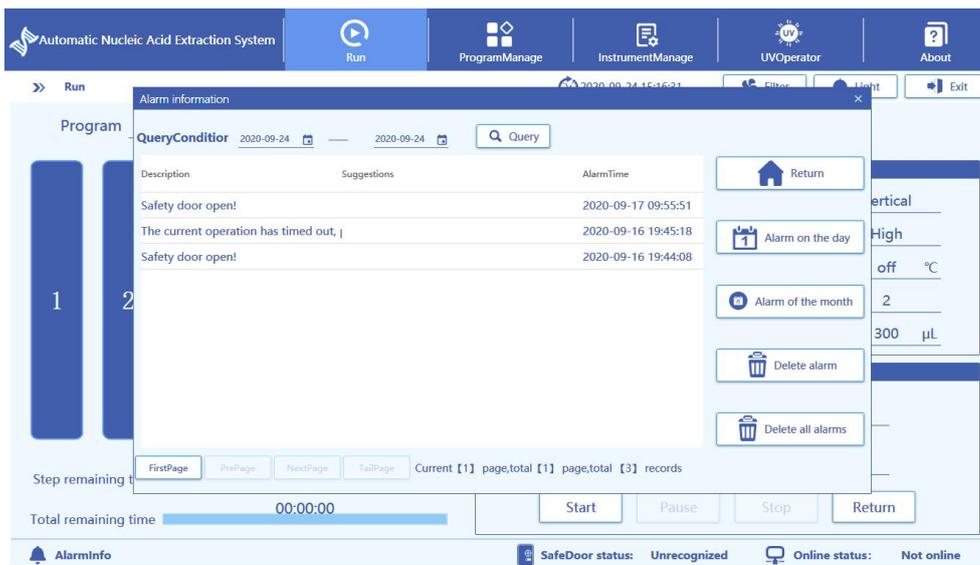


Figure 3-5

Common types of alarm information are as follows:

- Reset failure of magnetic rod and magnetic sleeve X!
- Magnetic sleeve Z reset abnormally!
- The magnet Z is reset abnormally!
- Cleavage temperature sensor abnormality!
- Elution temperature sensor abnormality bit!
- The cracking position oscillates abnormally!
- Elution bit abnormal oscillation!
- Safety door open!

Handling method after alarm:

- ① Open the safety door when the instrument is running, the safety door will alarm with a short alarm sound and automatically suspends. The instrument cannot automatically resume operation until the door is manually closed.
- ② Under the premise that the mechanical position of the instrument has not been altered without authorization, the instrument will usually not alarm except for the opening of the safety door. Once it happens, please contact the after-sales engineer immediately.

3.3 Program management

Click [Program Manage] to enter the program management interface as shown in Figure 3-6. All the programs that have been entered will be displayed in this interface, and the programs can be edited, deleted or added.

Add: Create a new program.

Edit: Select a program and click [Edit] to edit the parameters of the program.

Delete: Select a program and click [Delete] to delete this program.

Return: Return to the upper interface.

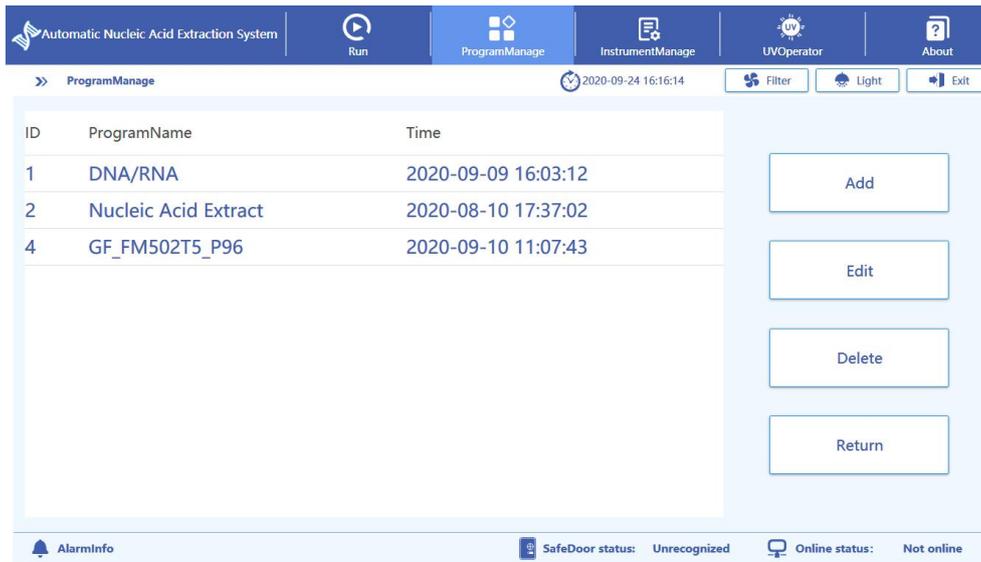


Figure 3-6

3.3.1 Add

Click [Add] to enter the interface as shown in Figure 3-7 to create a new program. Click [Add] after "Program Name" to set the program name, and the [Add] button is replaced with [Cancel]. After entering the program name, the following [Save] button changes from gray to clickable, click [Save] to save the program name settings.

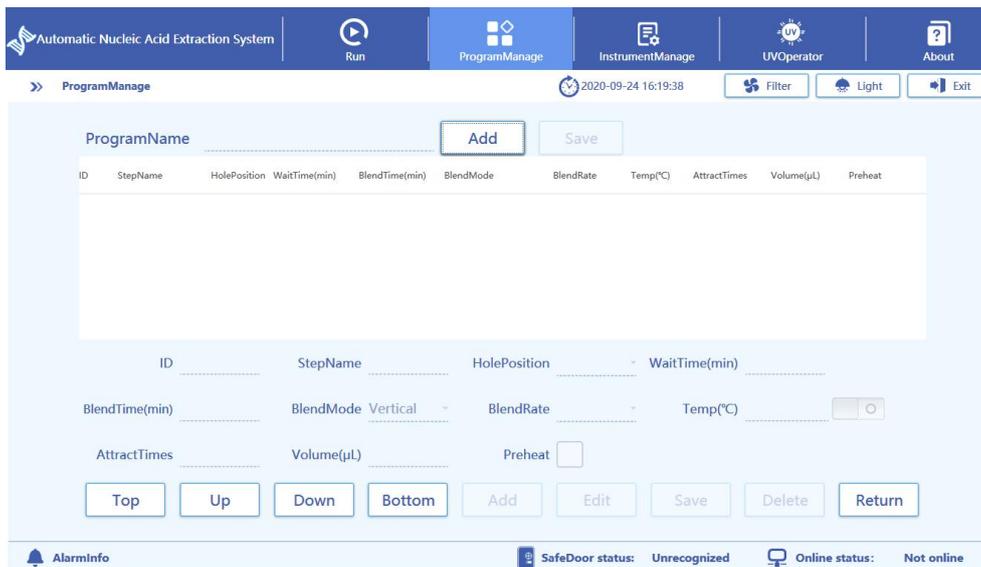


Figure 3-7

3.3.2 Edit

Select the program you want to modify in the "Program Manage" interface, and then click [Edit] to enter the "Program Edit" interface, as shown in Figure 3-8, where you can see each step of the program. Select a step to edit the parameters of that step.

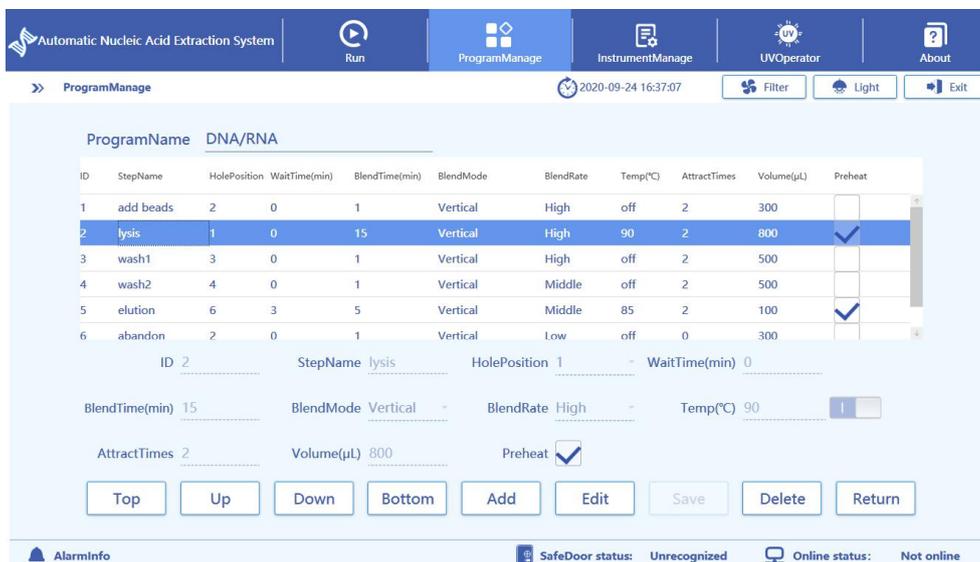


Figure 3-8

ID: The sequence of steps in the program. (Automatic generated)

Step Name: It is recommended to set the name of the step according to the requirements of the reagent instructions, which can be set freely.

Hole Position: The operation position of this step, column 1-6 is optional.

(The positions in column 1.6.7.12.13.18.19.24 have heating function, and the temperature control range is from room temperature to 100°C, that is, positions 1-8 in the instrument marked by numbers)

Wait Time: The standing time of this step is minute, and the upper limit is set to 99.

Blend Time: The shake time of this step is in minutes, and the upper limit is set to 99.

Blend Mode: Only vertical mode is available.

Blend Rate: Low, medium and high are available.

Temp: You can freely set whether this step needs heating and the heating temperature.

Attract Times: The times that the magnetic rod attracts the beads which can up to 99 times.

Volume: This volume corresponds to the volume of the solution in the well of the 96-well deep well plate. The rod sleeve will adjust the shaking distance in lysis and adsorption steps according to the volume, and calculate the time for one magnetization at this position.

Preheat: Preheat to ensure that the preset temperature is reached when performing this step.

Top: Set the selected step as the first step of the program.

Up: Run the selected step one step ahead.

Down: Delay the selected step by one step.

Bottom: Move the selected step to the last step of the procedure.

Add: Add a new step below the selected step.

Edit: Turn the above steps into editable state.

Save: It is usually grayed out. Click to modify and make changes to the steps to become clickable, and click it to save the changes.

Delete: Delete the selected step.

Return: Return to the upper interface.

3.3.3 System default program

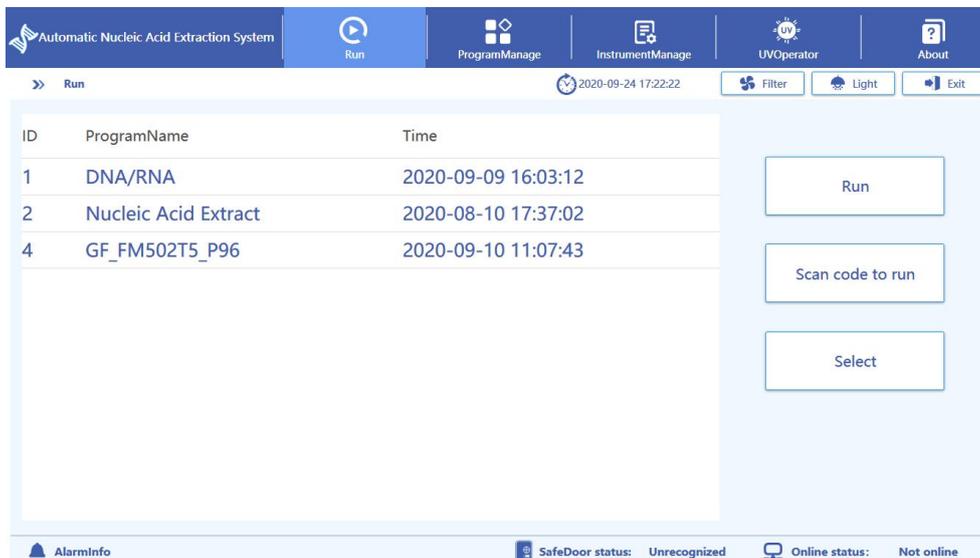


Figure 3-9

For example, select the "DNA/RNA" program, click [Select] to enter the interface as shown in Figure 3-10.

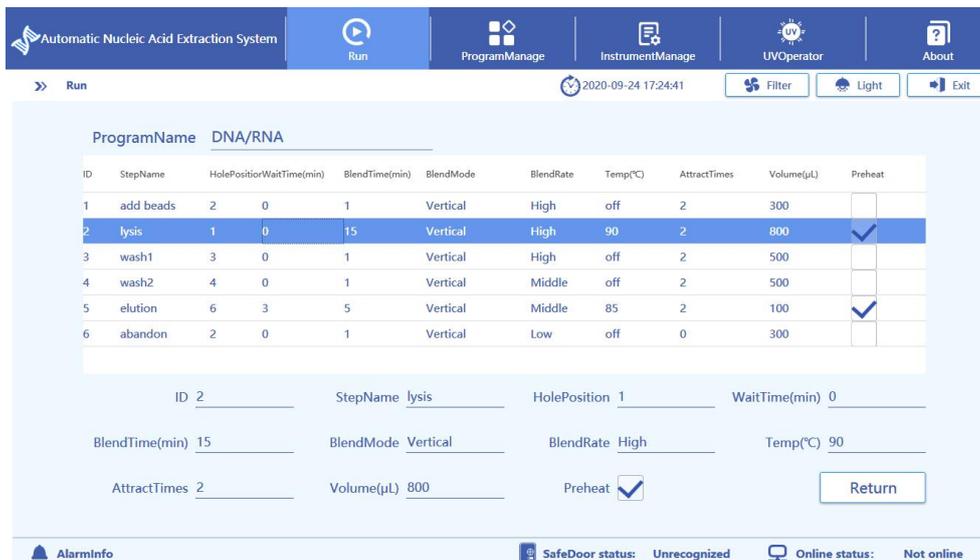


Figure 3-10

ID	Step Name	Description
1	Add beads	The operating position is in column 2 of the deep-well plate. There is no waiting time during the operation. The mixing time is 1 min. The mixing mode is vertical oscillation and the mixing rate is high. There is no heating demand. The number of magnetization is 2 times. This step The processing volume is 300ul.
2	Lysis	The operating position is in column 1 of the deep-well plate. There is

		no waiting time during the operation. The mixing time is 15 min. The mixing mode is vertical oscillation and the mixing rate is high. There is need to be heated to 90°C before operation. The number of magnetization is 2 times. This step The processing volume is 800ul.
3	Wash 1	The operating position is in column 3 of the deep-well plate. There is no waiting time during the operation. The mixing time is 1 min. The mixing mode is vertical oscillation and the mixing rate is middle. There is no heating demand. The number of magnetization is 2 times. This step The processing volume is 500ul.
4	Wash 2	The operating position is in column 4 of the deep-well plate. There is no waiting time during the operation. The mixing time is 1 min. The mixing mode is vertical oscillation and the mixing rate is middle. There is no heating demand. The number of magnetization is 2 times. This step The processing volume is 500ul.
5	Elution	The operating position is in column 6 of the deep-well plate. The waiting time during operation is 3min. The mixing time is 5 min. The mixing mode is vertical oscillation and the mixing rate is middle. There is need to be heated to 85°C before operation. The number of magnetization is 2 times. This step The processing volume is 100ul.
6	Abandon	The operating position is in column 2 of the deep-well plate. The waiting time during operation is 3min. The mixing time is 1 min. The mixing mode is vertical oscillation and the mixing rate is low. There is no heating demand. No magnetization. This step The processing volume is 300ul.

3.4 Program management

As shown in Figure 3-11, the instrument management interface has four functions: [Instrument Debug], [Import/Export], [Software Upgrade], and [Language Setting].

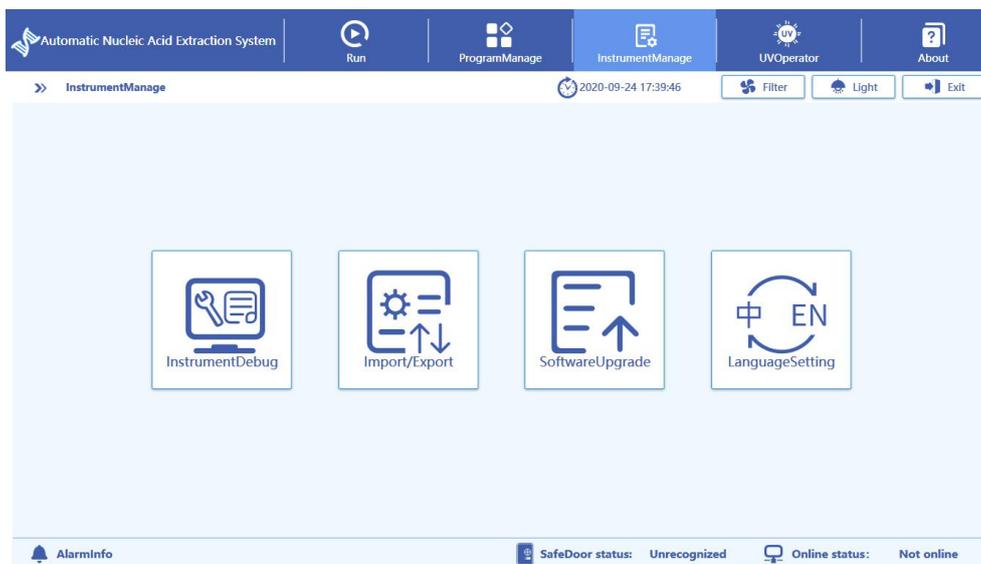


Figure 3-11

3.4.1 Language settings

Click [Language Settings] to switch the software between Chinese and English, as shown in Figure 3-12.(Need a password, you can contact the after-sales engineer.)

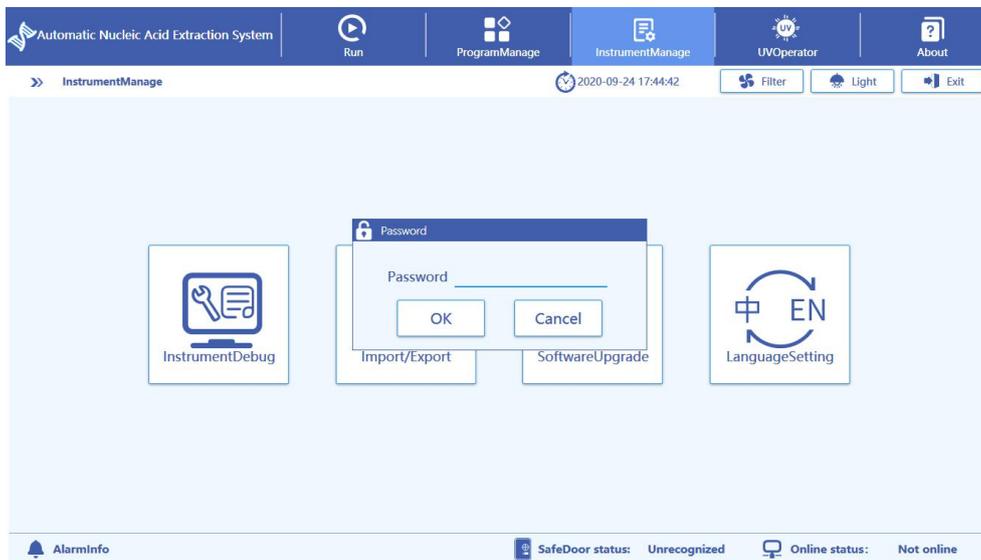


Figure 3-12

3.4.2 Instrument Debug

The “Instrument debugging” interface can set the instrument motion parameters and position parameters, which have been set before leaving the factory and usually not need to be modified.

3.4.3 Import/Export

Plug the U disk into the USB interface of the instrument to export the existing programs of the system to the U disk for storage. Similarly, after editing the program in the computer, you can import the program into the instrument via a USB flash drive. The interface is shown in Figure 3-13.

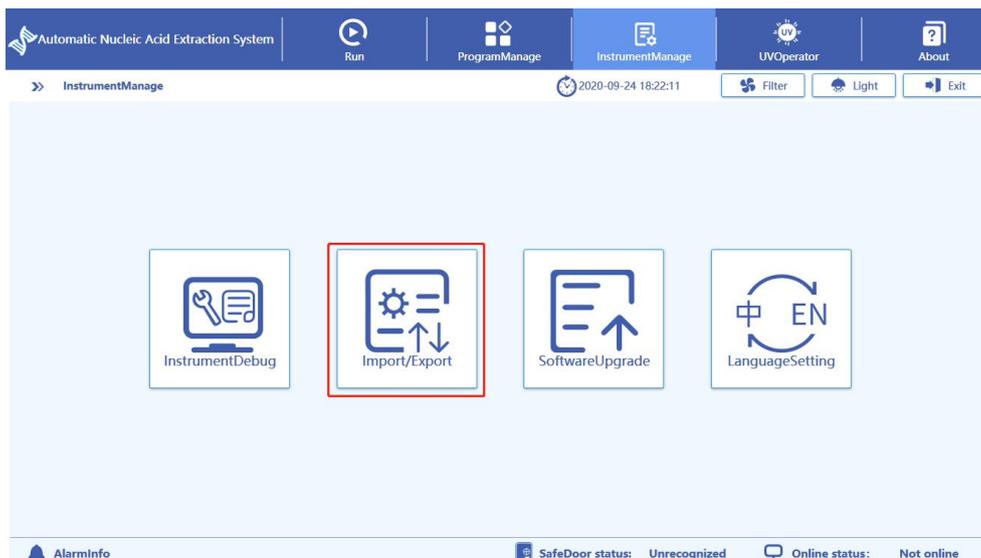


Figure 3-13

3.4.4 Software upgrade

Plug the U disk into the USB interface of the instrument, click [Software Upgrade], the interface is

shown in Figure 3-14. Click the circuit board module that needs to be upgraded, then select the .bin file that needs to be upgraded, and then click [Upgrade] to complete the module upgrade. As shown in Figure 3-15.



Figure 3-14

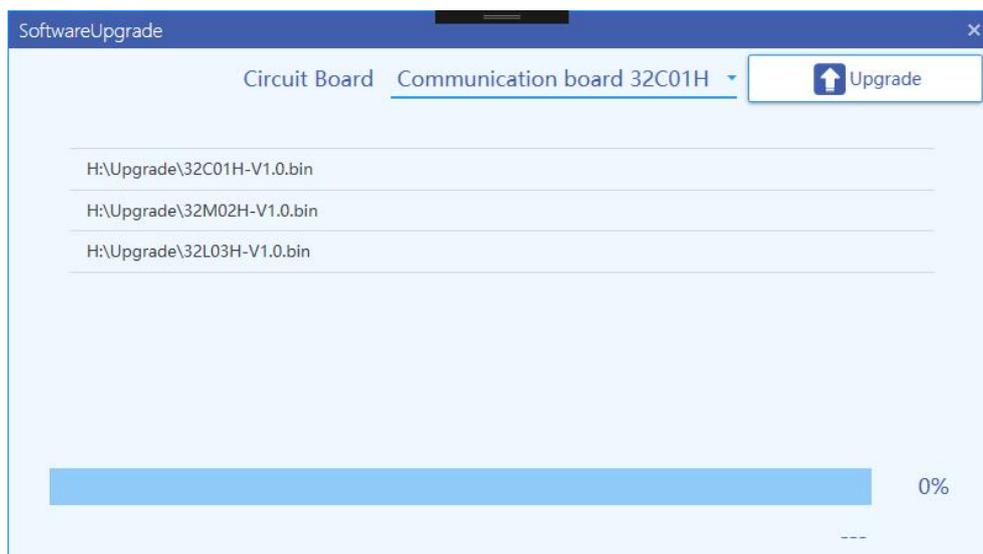


Figure 3-15

3.5 UV disinfection

Click [UV Operator] to enter the interface shown in Figure 3-16. You can set the UV disinfection time on the left, click [Open] to start disinfection and the time count down. After the countdown is over, the UV lamp is automatically turned off. You can also click [Stop] to stop the disinfection and turn off the UV lamp during the disinfection process.

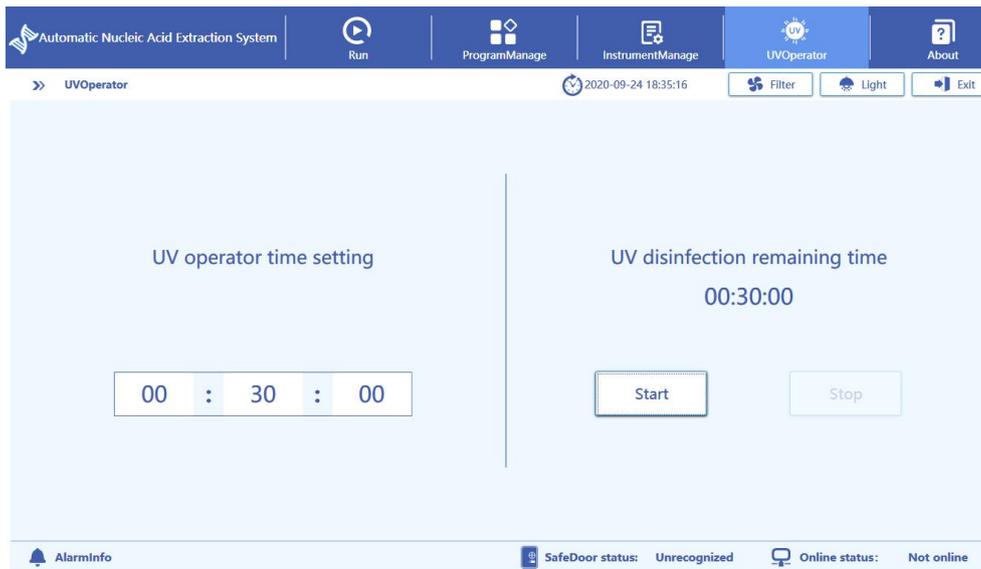


Figure 3-16

Note:

- 1) At the end of the disinfection time, the system will automatically turn off the UV lamp, or the operator can turn off the UV lamp according to the actual situation.
- 2) During the UV disinfection process, no icons except UV disinfection function can be used. Other icons can be used only when the UV lamp is off.

Warning: Do not look directly at the UV lamp when it is turned on to avoid accidents!

3.6 About

As shown in Figure 3-17, the "About" interface displays the current software version, machine code, motor driver board version, program version of the communication module and the temperature control oscillation module.



Figure 3-17

Run log: The operation record of the nucleic acid extractor, users generally do not need to check it.

Instruction: Built-in electronic version of the operating instructions of the nucleic acid extractor, click to view.



Figure 3-18

3.7 Exit

After clicking the [Exit] button in the upper right corner, a prompt box as shown in Figure 3-19 is displayed.

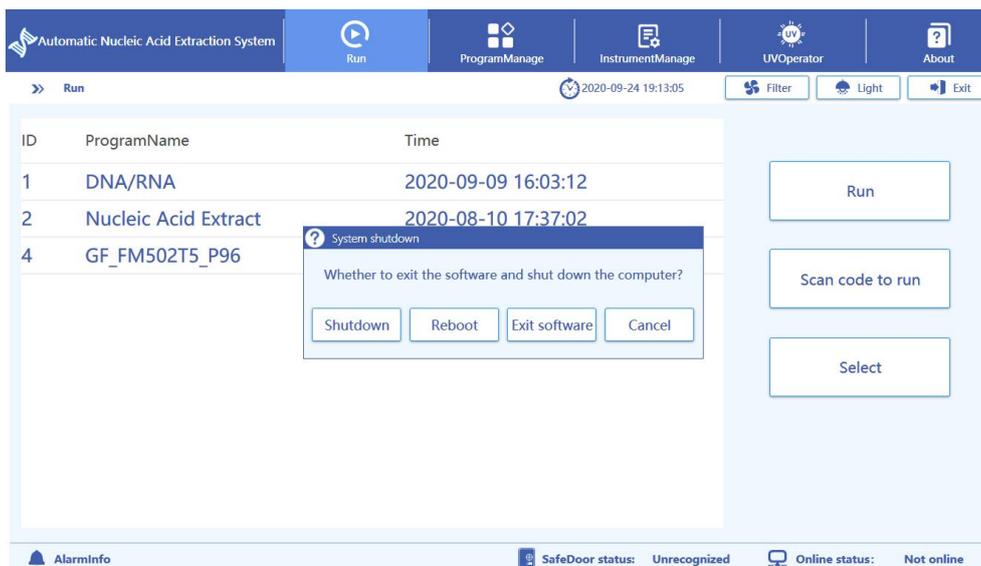


Figure 3-19

Shut down: Turn off the industrial computer.

Reboot: Reboot the industrial computer.

Exit software: Only exit the software, the interface returns to the main interface of the industrial computer.

Cancel: Cancel the operation of the previous step.

4.Maintenance

- 1) Please read the operating instructions carefully before using the instrument.
- 2) After the testing, turn off the power supply of the instrument. Please use absorbent cotton dipped in 75% ethanol for wiping the cabin instead of pouring ethanol into the cabin directly. After the ethanol is dried, turn on the UV lamp to disinfecting more than 30 minutes.
- 3) Regularly clean the surface and cabin of the instrument, and be careful not to use strong alkali, concentrated alcohol and organic solvent solutions.
- 4) Keep the environment in the cabin dry and free of water stains.
- 5) Do not use the instrument in a dusty environment.
- 6) During the use of the instrument, please ensure that there is good ventilation around the instrument.
- 7) Please do not use the instrument when the voltage is unstable, too high or too low.
- 8) When the instrument is not in use for a long time, please unplug the plug and cover the instrument with a soft cloth or plastic bag to prevent dust.
- 9) When the instrument is not in use, in order to ensure the stable performance of the instrument, it is recommended to run the instrument on empty every 30 days.
- 10) If the rod cover is worn out during use and the magnetic rod is contaminated, use absorbent cotton dipped in absolute ethanol to wipe it in time. After the absolute ethanol evaporates, turn on the UV operator for 30 minutes.

Warning: It is forbidden to clean the cabin or surface during instrument running.

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