M007-2EN

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C/ Horacio Lengo, 18. 29006. Málaga. Spain

M96 Automatic Nucleic Acid Extraction System

(Manual)

Biocomma Limited

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05/2020
Biocomma Limited

-Content-

installation package provided by Biocomma.

■ When startup or operate the user software, it is forbidden to change the date and time of the host.

■ When the user software is running, it is forbidden to run other applications.

■ It is forbidden to open, edit and delete the experimental program while the instrument is running.

11. Manufacturer information

Manufacturer: Biocomma Limited

Manufacture address: B1605-B1606, Life Science Park, Shenchengtou Creative Factory, Julongshan Rd, Xiuxin Community, Kengzi St, Pingshan Dist, ShenZhen, 518118, P.R.China

Customer service address: Ground FL, Bdg 12, Zhonghaixin Innovative Industrial Park, Ganli Six Rd, Buji St, Longgang Dist, Shenzhen, 518114, P.R.China

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Record certificate number: Guangdong Food and Drug Administration Production preparation No. 20200010

Medical device filing certificate number: Guangdong Food and Drug Administration Production preparation No. 20200084

12. Specification approval date and revision date

Approval date: March 20, 2020

Revision date: May 8, 2020

Biological risk protection

In order to effectively protect against biological risks, please comply with the following precautions.

Warning:

■ All liquids and solids in the laboratory are considered to be biohazardous, and users must take general laboratory precautions.

■ All clinical samples are considered to be infectious. Improper use may lead to infection. Please do not directly touch the samples with your hands. Be sure to wear gloves and work clothes to prevent infection during operation. Wear protective glasses if necessary.

■ If the sample, etc. comes into contact with the skin, please immediately handle it according to the user's working standards and consult a doctor.

Waste Treatment

To prevent environmental pollution and personal injury caused by waste products, please observe the following precautions.

Warning:

■ After handling the samples, reagents and other wastes, please comply with the relevant local laws and regulations.

Other notification

In order to use the instrument correctly, please comply with the following precautions.

Warning:

■ No smoking and eating near the instrument.

■ Avoid direct lighting during operation.

■ When installing user software, please use the software

Introduction

Thank you very much for using M96 automatic nucleic acid extraction system. Please read this manual carefully before using the system, especially the precautions, warnings and prompts. Please keep the manual at approaching place for convenient use.

The user should be professionally trained for operation, operator without training is forbidden for safety purpose.

Information

Product name: Automatic nucleic acid extraction system

Model Specification: M96

Cat No.: NAES-96

Software Name: Human-computer interaction control software

Software Version: V3

Software Name: Automatic nucleic acid extraction software

Software Version: V1

Dimension: 760mm(L)×480mm(W)×570mm (H)

Net Weight: 59kg

Production Date: details as label.

Life Expectancy: 5 years

1. Overview

1.1 System Introduction

M96 is an integrated nucleic acid extraction system that can purify nucleic acids from a variety of biological samples including whole blood, viruses, tissues, plants, bacteria and cultured cells. With intelligent pre-installed extraction programs and magnetic bead-based nucleic acid extraction kits and consumables, this system can provide laboratories with efficient, automated, high-quality nucleic acid purification solutions for downstream genetic analysis and molecular diagnostics.

1.2 System Structure

Automatic nucleic acid extraction system consists of mechanical parts and electrical parts including shell, cover, sample blending part, magnetic bead transfer part, heating and cooling part, UV sterilization part, color touch screen, application software for automatic nucleic acid extraction based on PLC platform.

1.2.1 System Front View

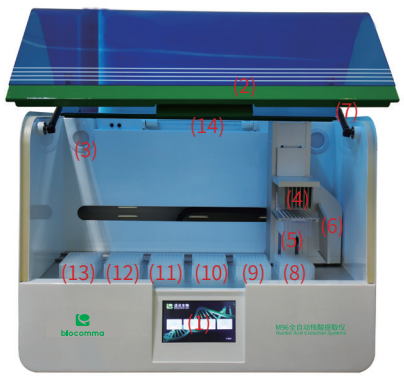

Fig 1. System Front View

(1)	Touch Control UI	(2)	Hatch Door
(3)	Light	(4)	Magnetic Bar
(5)	Magnetic Cover	(6)	Rotatable Stillicide Apron
(7)	Air Pressure Support	(8)	Station I
(9)	Station II	(10)	Station III
(11)	Station IV	(12)	Station V
(13)	Station VI	(14)	UV lamp

must be closed, and body parts must not be extended into the machine working area; unless the system has stopped working, the door can be opened to place samples, reagents,pipette tips, etc., otherwise it may cause injury to the operator. At the same time may cause damage to the instrument. Please note the following possible mechanical hazards:

■ Robotic arm causes crush injury

Prevent fire and explosion

To prevent fire and explosion, please comply with the following precautions.

Warning:

■ Watch over alcohol is flammable when using

Electromagnetic interference prevention

To prevent electromagnetic interference, please comply with the following precautions.

Warning:

■ In order to ensure the instrument operate normally, the user must ensure the device operatin in electromagnetic compatibility environment.

■ Electromagnetic interference may affect the instrument's normal operation. No install the instrument in an environment with strong electromagnetic field interference.

■ No use other medical instrument that may generate electromagnetic interference to work around the instrument, otherwise it may affect the instrument to operate normally.

■ This instrument complies with EMC requirements. The instrument may generate radio frequency interference in the indoor environment,so pls take appropriate measures to reduce the interference.

■ When the main power of the instrument is turned on, unauthorized maintenance personnel should not disassemble the instrument shell.

■ If the solution spills into the instrument, it may cause malfunction and electric shock. Please do not place objects on the instrument. In the event of spillage, please immediately turn off the power and contact the user service department of Biocomma. or the local service representative.

■ Do not plug or unplug the power supply with wet hands.

■ Before turning on the instrument for any maintenance or repair, disconnect it from all power sources. If such work must be carried out, it can only be maintained by personnel who understand its hazards and are skilled in operation.

■ Make sure that the replaced power supply meets the requirements of this instrument.

■ If the instrument may have been damaged, you should disconnect the power socket and do not operate it again.

Electrical Hazard

To prevent electrical hazards, please observe the following precautions.

Warning:

■ The operator must always observe the electrical safety operation specifications. Only professional personnel can carry out electrical maintenance. During maintenance, please wear an anti-static wrist strap or gloves to protect the sensitive components on the equipment from electrostatic damage.

Mechanical hazards

To prevent mechanical hazards, please comply with the following precautions

Warning:

■ The moving parts of this system may cause personal injury during operation. During the experiment, the instrument door

1.2.2 System Rear and Side View

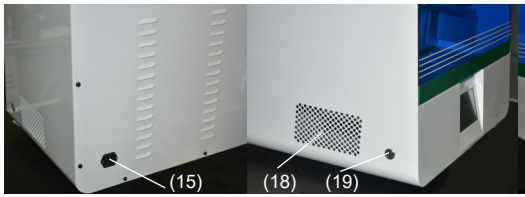

Fig 2. System Rear View

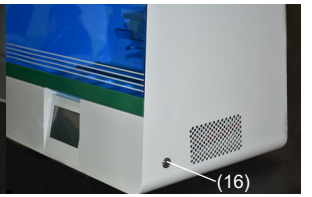

Fig 3. System Side View

(15)	Supply hub	(16)	On-off key
(17)	Heat emission hole	(18)	Heat emission net
(19)	Light switch		

1.2.3 System Details

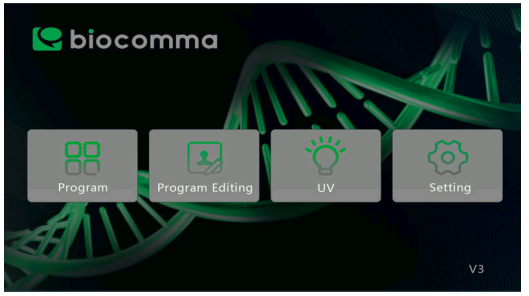

Fig 4. LCD Front View

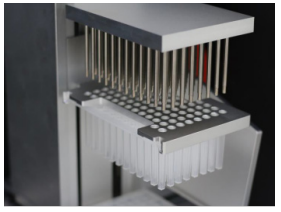

Fig 5. 96 Magnetic bars horizon down magnetic cover

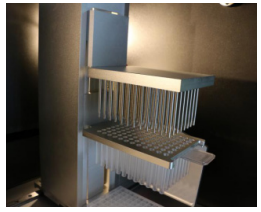

Fig 6. 96 Magnetic bars vertical down magnetic cover

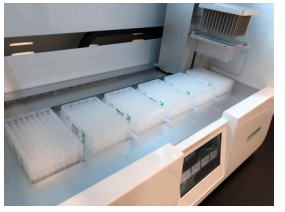

Fig 7. 6 Operation parts

1.3 Intended Use

For the extraction and purification of nucleic acids in clinical samples.

2. System Operation Principle

The principle of this product is the magnetic bead adsorption method.

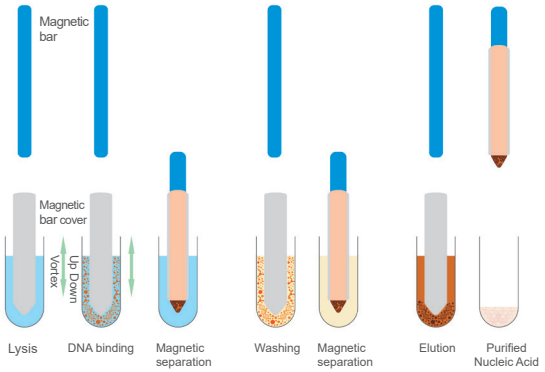

Fig 8. Magnetic bead nucleic acid extraction schematic

Automatic nucleic acid extraction system can operate up to 96 samples simultaneously. Use the magnetic bar on the magnetic bar holder of the experimental cabin to move the magnetic beads adsorbed with nucleic acids to different reagent wells, and then use the magnetic rod cover placed on the outer layer of the magnetic bar to repeatedly and quickly mix the liquid up and down to make the liquid and Magnetic beads are uniformly mixed, and after cell lysis, nucleic acid adsorption, washing and elution, high purity nucleic acid is finally extracted.

3. Performance parameters

3.1 Performance Index

3.1.1 Performance

3.1.1.1 Processing capacity: 1 to 96 samples, different accessories can be selected to meet different throughput requirements;

3.1.1.2 Processing time: 15 min ~ 60 min (depending on the kit used);

3.1.1.3 Working volume: 20 μL ~ 1 mL, absolute elution volume: 20 μL;

3.1.1.4 Recovery rate of magnetic beads:> 99%;

3.1.1.5 Permanent magnet magnetic column: 3000 Gs ~ 6000 Gs, replaceable accessories, flexible choice;

3.1.1.6 Clean function: with UV sterilization function and exhaust function

10. Safety Precautions

In order to use this system safely and effectively, please read the following safety precautions carefully. Any operation that violates the following safety precautions may cause system damage or personal injury. If the userdisobeys the instructions to use the system, the protective measures provided by the system may fail.

Electricity Safety

To use electricity safely and prevent electric shock and instrument damage, 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 overcurrent protection devices, these switches or circuit breakers should be placed near the equipment.

■ Do not place the device in a position where it is difficult to operate the disconnect device. If the power plug cannot be disconnected immediately in an emergency, make sure that the wall socket for connecting the instrument power can be touched at any time.

■ After the installation is completed, customers are not allowed to move the device without permission. If you must move the device, please contact the installation engineer for on-site service.

■ The system is grounded through the ground wire of the power cord. To avoid electric shock, the ground wire of the power cord must be grounded.

■ The AC power supply must be stable, and it is forbidden to share the power supply with high-power appliances.

■ Do not touch the power connector at the rear of the system when the user is operating or maintaining the instrument, otherwise there may be a risk of electric shock.

9. Logos, Labels and Symbols

Logos, labels, symbols, etc. are the reminder for users to pay attention to the precautions or potential dangers in use, please use them together with the text.

SN	Product serial number
IVD	For vitro diagnostic use only
	Biohazard: Remind users to follow the instructions, otherwise there is a risk of biological pollution.
	Warning: Special reminder, use according to the requirements of the manual.
	Warning electric shock: please refer to the detailed instructions on the manual, and operate carefully.
	During operation, there is a risk of crushing, puncture or injury from moving parts; please refer to the detailed instructions. Make detailed instructions and proceed with care.
	This way up: Indicates that the correct position of the transport package is vertically up.
	Fragile, handle with care: Indicates that the shipping package contains fragile products, and care should be taken when moving.
	Keep away from rain: The package should avoid moisture.
	Packages are not allowed to stack.
	Consult instructions for use
	On (Main instrument power supply)
	Off (Main instrument power supply)
	Alternating Current
	Manufacturer
	Production Date
	Be Carefull With Hand
	Grounding Mark
	Hot Surface, Do not tunch

3.1.2 Appearance

3.1.2.1 Automatic nucleic acid extraction system consists of a casing, a mechanical movement mechanism, an ultraviolet sterilization mechanism, a heating and temperature control mechanism, and a control system. The outer cover of the cabinet is made of white transparent acrylic material, and the outer surface should be flat and smooth without any defects such as bumps and scratches. The shell is made of metal and its surface is treated with white matte paint. The surface should be flat and smooth, and the color should be soft and uniform. There should be no defects such as exposed bottom, bubbles, peeling, cracking, whitening, sagging, abrasion, pinholes, orange peel, etc. Directly in front of the machine is a 7-inch color resistive touch screen. The tilt is facing the user, which greatly improves the operating comfort.

3.1.2.2 Fastener connection shall be firm and reliable, there shall be no looseness, and screws shall be installed at fixed holes;

3.1.2.3 Silk screen printing shall not have ghosting, ink overflow, missing corners, missing prints, misalignment, less ink, etc., and the silk screen graphics have strong adhesion;

3.1.2.4 The 96-well plate placement table uses a push-pull design, which makes it easier to put consumables.

3.1.3 Software application functions

Through software interface operation, you can control the horizontal and vertical movements of the equipment movement module, temperature of heating module, ventilation, lighting device and UV sterilization device.

3.1.3.1 You can set the program name, hole position and step, liquid volume, set waiting time, set mixing time, set mixing speed, set magnetization time, set lysis temperature, and set elution temperature.

3.1.3.2 For horizontal movement, the manipulator can input the corresponding position and speed parameters through the human-machine interface on the color touch screen. The sequence and time of each action during operation should be consistent with the set parameters. The manipulator moves without interference, no abnormal sound, No kick.

3.1.3.3 Vertical movement, sample mixing and magnetic absorption, the corresponding position and speed parameters can be entered through the human machine interface on the color touch screen. The sequence and time of each action during operation should be consistent with the set parameters. The magnetic rod

and magnetic cover shall be centered in the deep-hole plate without interference and abnormal noise;

3.1.3.4 Enter the UV lamp setting interface and press the Run or Stop key to turn the UV lamp on or off.

3.2 Features

◆ Temperature module: Excellent temperature control ability, which can keep the module at 4 ~125°C.Through semiconductor refrigeration technology, the temperature can quickly reach the set value. After the extraction is completed, the temperature of station 6 is automatically reduced to 4°C, and the DNA is stored;

◆ Sample protection: M96 has functions such as poweron self-test, power-off protection, high- temperature alarm, and over-temperature protection, which can minimize the loss of samples during the use of the instrument;

◆ Optimized motion design: the use of modular linear motion design makes it more convenient for users; Motor protection: The magnet motor remains stationary during work, which extends the life of the magnet motor and the slide rail;

◆ Ultra-quiet operation: unique structural design, low mechanical sound during operation, and does not affect the laboratory environment;

◆ Autonomous programming control: the program can be visually touched and freely edited, and it can be stored > 100 groups of programs;

◆ Open platform: suitable for multiple nucleic acid extraction schemes based on nano-magnetic beads;

◆ Pollution control: The unique sample cross-contamination control system effectively prevents sample contamination.

4. Nucleic acid extraction instructions

4.1 UI introduction

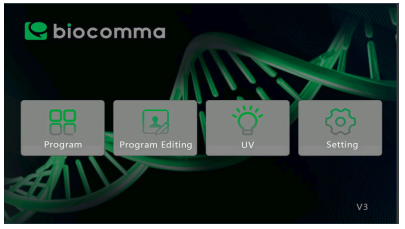

Fig 9. UI main menu

C. It should be hardware problem if still no response, please contact after sales service.

7) When liquid enters the instrument or the instrument is subjected to a major mechanical impact, the power should be cut off immediately and contact the after sales as soon as possible.

8) The fuse of the M96 nucleic acid automatic extraction system is 250V, 5A.The fuse is installed under the power jack on the back of the system, user can replace it. When you need to replace the fuse, please follow the steps below:

A. Power off the power and unplug the power cord;
B. Take out the safety seat on the left side of the power socket;
C. Take out the fuse, check whether the fuse is damaged, if it is damaged, replace it with a new fuse;
D. Reinsert the fuse holder and turn on the power.

7.3 Storage/transportation condition

Transport Condition: Driving Speed ＜ 40km/h

Storage Condition: -40℃ -55℃

8. After-sales Service

Provide on-line service for pre-sale guidance, after-sale installation, commissioning, use, maintenance and other services. The instrument is guaranteed for 1 year. After the warranty period, paid service is provided.

Notices:

Biocomma shall be released from all obligations under its warranty in the event repairs or modifications are made by persons other than its own personnel, except in cases where the company has given its written consent to perform such epairs or modifications.

All materials replaced under this warranty will be warranted only for the duration of the original warranty period, and in no case beyond the original expiration date of original warranty unless authorized in writing by an officer of the Company.

7.2 Common Faults and Troubleshooting

1) No display on the screen

A. Check if the machine was turned on

B. Ds the power cord plugged in?

C. Whether the power outlet has power

D. Please contact after sales service if still unable to boot.

2) The instrument cannot complete the self-test, or cannot continue to run during operation, and emits abnormal sounds

A. Check if there is any foreign objects on the track to prevent the robotic arm from moving?

B. Are there any foreign objects on the magnetic bar holder?

C. Is the magnetic bar cover not inserted in right place?

D. Is the 96 well plate correctly placed into the work station?

E. Please contact after sales service if the program still can't run normally.

3) Instrument down

A. Use the power switch on the back of the instrument to restart the instrument.

B. If still no response after several times restart, please contact after sales service

4) UV light doesn't work

A. Restart the instrument, turn it on again, and check whether it is caused by the downtime.

B. Check if the UV lamp is in good contact

C. Replace it with new UV lamps

5) There is magnetic beads remain in a few wells.

A. Check the magnetic bar to see if it is dirt or damage

B. Use magnet to detect demagnetization of magnetic bar

6) Heating block does not heat or cool

A. Is the heating temperature and time incorrectly set?

B. Restart the instrument, and check whether it is caused by the downtime.

Main menu keys from left to right: <Program menu>, <Program editting>, <UV lamp>, <Setting>.

4.2 Program run

Step 1, Supply power for the system, turn on the right power switch, the system is started and begins to do self-check, then it comes to the following boot screen after self-check, now it is in originalstate.

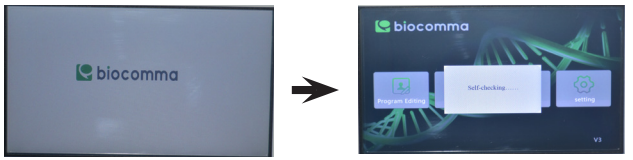

Fig 10. System boot screen

Step 2, Click "Program" into the program selection interface. Users can do program search by clicking corresponding keys( ) page left and right (,)add new program ( )delete program ( ) back to main page ( ) etc.

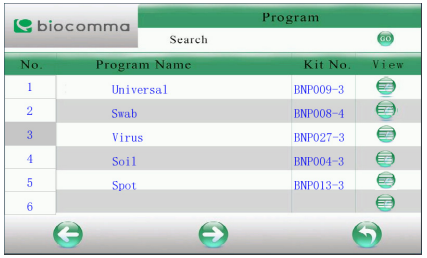

Fig 11. Program selection interface

Step 3, click "Program Editing" Enter the management password "8306 ( ) to enter into program editing interface. Users can can turn down and turn up pages by corresponding keys (, , program storage , return to previous menu ( ), etc. Users can set up "boot interface","washing station sequence","waiting time","blending time","blending speed","magnetic absorption time","cracking time","elution time","4℃ storage temperature" by clicking the corresponding key number.

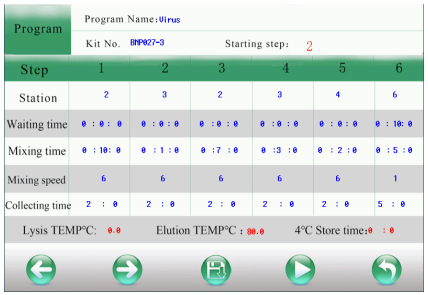

Fig 12. Program editing

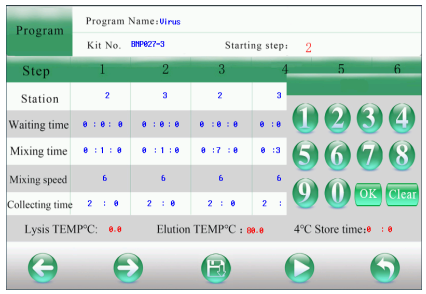

Fig 13. Parameters setting

Step 4, Click "Program Save"( ), the system will remind you of successful program save by automatic pop-up news; Click "Close" and click "Program Run"( ) to enter into the program run interface.

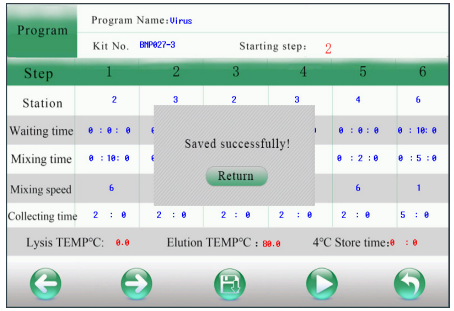

Fig 14. Successful program save interface

more than 30minutes to disinfect it. Avoid contact with strong corrosive liquids and avoid mechanical impact. Do not use cleaning agents or disinfectants that chemically react with equipment parts or materials contained in the equipment to cause danger; if there is doubt about the compatibility of the disinfectant or cleaning agent with the equipment parts or materials contained in the equipment ,please consult the manufacturer or distributor.

3) Ensure that the instrument operating environment could provide stable voltage, suitable operation humidity and temperature which meet the requirement. The table on which the instrument is placed should be stable.

4) Make sure the magnetic bar sleeve was covered on the magnetic bar to avoid contamination by contacting reagent. If the magnetic bar was contaminated, wipe it carefully with 75% alcohol or ddH2O and clean cotton cloth.

5) Do not open the instrument to replace components or perform internal adjustment without training or authorization, it must be operated by professional maintenance personnel after being approved by our company.

6) Attention to the electricity safety, do not operate with wet hands;

7) It is strictly forbidden to touch the heating block with bare hands when program running to avoid burns.

8) After the program ends, it will ring, click the “back” key, you will return to the home page.

9) Any parts of the instrument could only be inspected or supplied by the manufacturer or distributor.

10) It is necessary to check whether the fan of the instrument works properly every quarter.

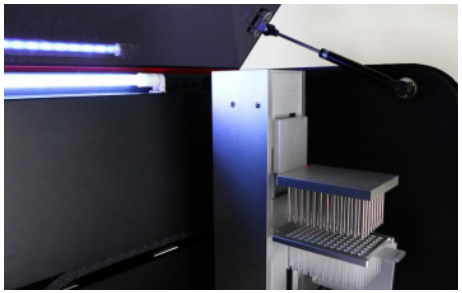

Fig 19. UV lamp turned on

6.3 Pause and stop function

During program run, users can pause the program by clicking "Start/Pause"( ), or stop the program by clicking "stop"( ) and return to the main page by clicking"Return"( ).

Notice: The mechanical arm will stop move after clicking "Pause", but the station will not change, the program can continue the program later. If stopped, the program will stop, the mechanical arm will return to the original station automatically.

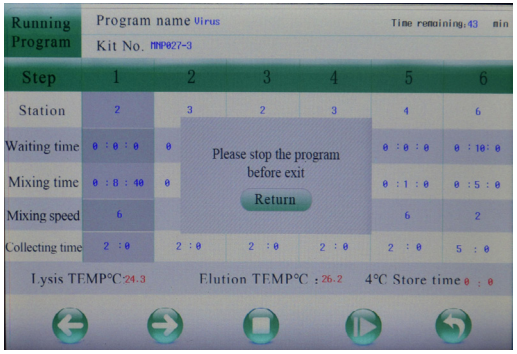

Fig 20. Program stop

7. Attention

7.1 Instrument maintenance and safety

1) Read the manual and watch the instruction video carefully before using the instrument.

2) Regularly clean the instrument with 75% ethanol, and turn on the UV lamp for

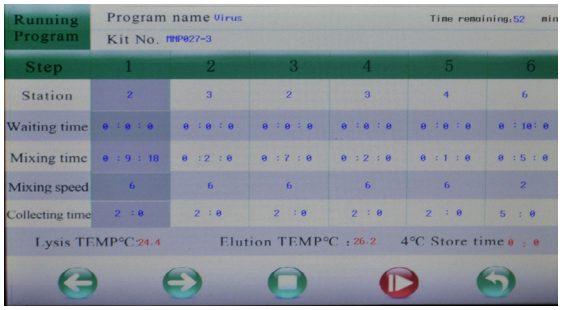

Fig 15. Program run interface

Step 5, put magnetic bars in magnetic bar support, put the deep hole plate in the corresponding station, click "Start/Pause"( ), the system begins to run its program.

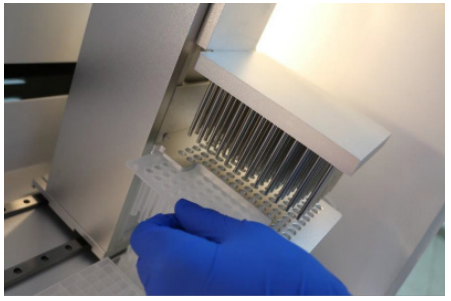

Fig 16. Use of horizon down magnetic cover

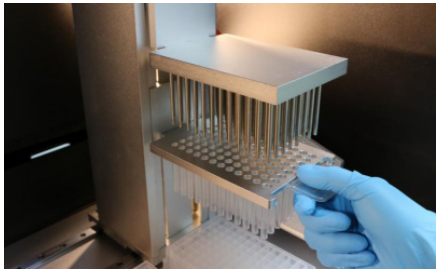

Fig 17. Use of vertical down magnetic cover

Step 6, After program run, the system will stop automatically and give out buzzing sound to remind users.

5. Installation Instruction

5.1 Installation environment requirement

M96 Automatic Nucleic Acid Extraction System must be installed and used in below environmental condition:

◆ Environment Temperature: 10~30℃

◆ Relative Humidity: 30%~80%

◆ Altitude:Below 2000meters

◆ Power Supply: 100-240V~, 4.0A 50/60Hz

◆ Well ventilated, avoid direct sunlight

◆ The desktop for the instrument should be flat, bigger than 80cm (length)×70cm (width)×80cm (height), and stable enough to bear more than 100kgs weight.

5.2 Open Package

M96 Automatic Nucleic Acid Extraction System are stored and transferred in flight case, below is the packing list:

Serial No.	Content	Qty
1	Automatic Nucleic Acid Extraction System	1EA
2	Manual	1EA
3	Power cord	1EA
4	Product guarantee card	1EA
5	Packing list	1EA
6	Testing report	1EA
7	Magnetic bar cover	4PC
8	After-sales service card	1EA
9	Fuse	2EA

Notice: The equipment must be installed by professionally personnel trained by the manufacturer's video. It is prohibited for the personnel without training to install the equipment. Otherwise, the equipment may be damaged.

5.3 Optional accessories

M96 Automatic Nucleic Acid Extraction System can replace its accessories for different use, as follows:

Serial No.	Accessory name
1	96 well plugboard
2	24 well plugboard
3	Quickset plugboard
4	96 well magnetic bars
5	24 well magnetic bars
6	96 well heating board
7	24 well heating board

Notice: please consult us for use of the accessories. The accessories should be replaced by trained workers. Untrained workers are forbidden of the replacement of the accessories, it may lead to harm of the system.

6. Other instructions

6.1 Power-off Protection

If power is cut off during program run, the system will save its program run state, when the system is re-powered, it will remind users whether continue it previous program, users can click "Yes" to continue the previous program or click "No" to start a new program.

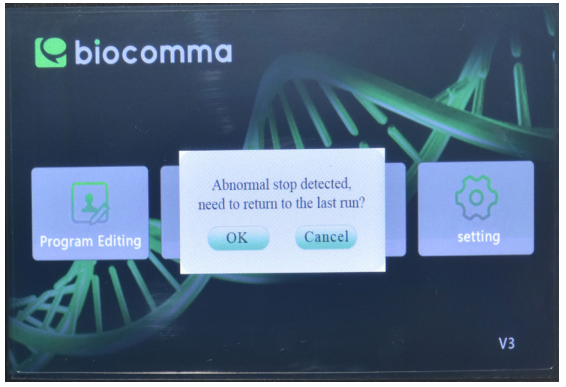

Fig 18. Power-off protection function

6.2 Ultraviolet lamp disinfection function

Click UV Lamp"( " on the main interface to set up regular schedules for sterilization.