

GENFINE

Purifier HTS

User manual V1.0

GENFINE BIOTECH (CHANGZHOU) CO., LTD.

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Chapter 1 Product Introduction

1.1 Product Name

Automatic Nucleic Acid Extractor

1.2 Model

Purifier HTS

1.3 Intended Use

Purifier HTS (Figure1-1) adopts the magnetic beads separation technology to achieve the collection, release, transfer and incubation of the magnetic beads through the movement of the magnetic rods and the magnetic tip combs. And by this, it can complete the entire nucleic acid extraction process.

The instrument can be applied for the extraction and purification of nucleic acid from different clinic samples. Purifier HTS is especially used on research and tests by the personnel who have been trained professionally. It is used for automatic transfer and processing of magnetic beads in deep well plates. It is recommended that good laboratory practice (GLP) should be followed to ensure the reliability of the analysis. Refer to Chapter 6: Technical Parameters.



图 1-1. Purifier HTS

Chapter 2 Function Introduction

2.1 Main Components

2.1.1 Front View



Figure 2-1 Purifier HTS Front view

2.1.2 Rear View

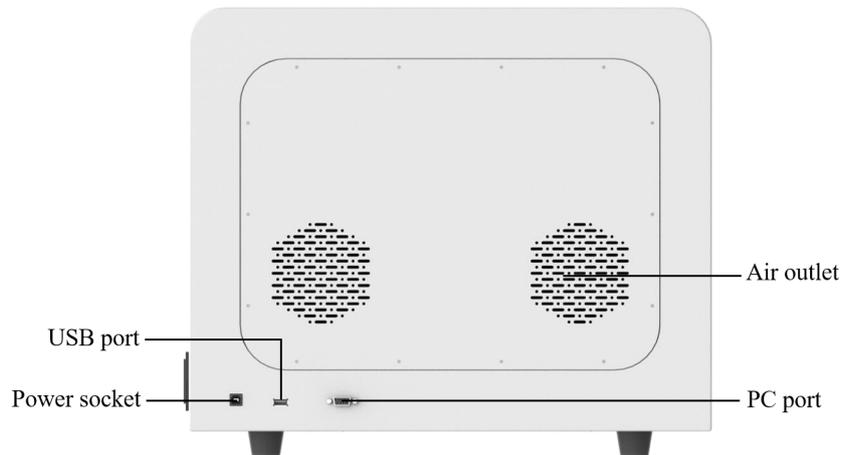


Figure 2-2 Purifier HTS Rear View

2.1.3 Inside View



Figure 2-3 Purifier HTS Inside View

Purifier HTS (Figure 2-3), The magnetic tip combs matches the deep-well Plate. The magnetic head consists of two vertically moving platforms. One is used for the magnetic tip rods and the other is used for grasping the magnetic tip comb. During running, the magnetic tip comb and the magnetic rods move vertically to complete the mixing of reagents and the adsorption and release of magnetic beads.

There are 4 plate positions on the rotary table. Up to 4 pieces of 96 deep well plates can be placed simultaneously. Prior to the start of program, the samples and reagents are sub packed into the deep well plate according to the extraction scheme. In each step, the deep well plate remains stationary, and the moving component is the magnetic rod with magnetic rod tip comb.

The housing must be closed during operation. It can protect the sample from environmental contaminants.

2.2 Working Principle

Purifier HTS automatic nucleic acid extractor adopts magnetic beads separation technology (Figure 2-4). In this method, a disposable magnetic rod tip comb is loaded on the magnetic rod, and then the magnetic beads are transferred between the deep hole plates containing specific reagents through the separation of the magnetic rod and the magnetic rod tip comb, so as to realize the collection, release, transfer and incubation of the magnetic beads. Different from the traditional nucleic acid extractor, Purifier HTS contains two heating plates and two standard plates. Only four plates can complete the complete steps of nucleic acid extraction by magnetic bead method, so as to realize the high-quality extraction of nucleic acid in the sample, which greatly shortens the extraction time.

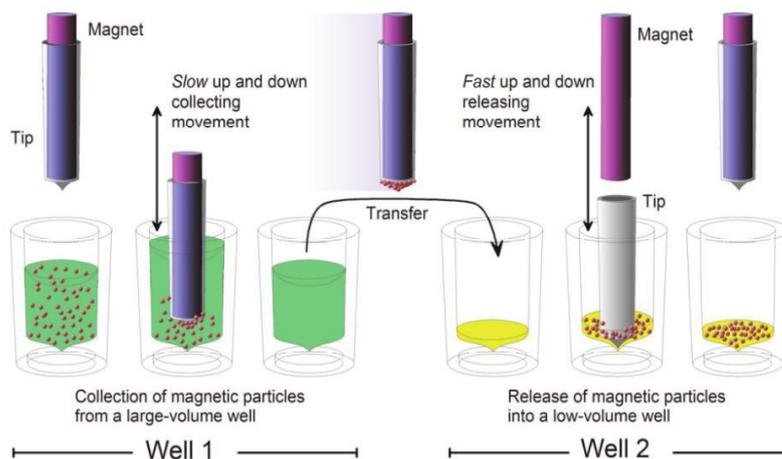


Figure 2-4. Diagram of working principle of the instrument

2.3 USB Port

There is a USB port on the front panel for importing and exporting programs.

2.4 Consumables

See "Accessory and Consumables List" for details and ordering information about Purifier HTS's consumables, such as deep well plates, magnetic rod tip comb, and HEPA filters.

Chapter 3 Installation

3.1 Deliver Check

3.1.1 Unboxing

Move the packaged instrument to the operation site. To prevent condensation of water vapor, the instrument should be left in its protective, anti-static plastic packaging until the ambient temperature is reached room temperature. Open Purifier HTS and accessories carefully. Remove the instrument from the package and place it on a horizontal surface.



Caution Be careful not to touch or loosen screws or parts specially specified the in the instruction manual. Otherwise, it may result in misplacement and invalidate instrument warranty.



Warning Purifier HTS weighs about 27 kg, if transporting without package, please handle carefully. It is recommended that two people move the equipment together and take appropriate precautions to avoid injury.

Please keep the original packing materials for future transportation. The packing is designed to ensure safe transportation and reduce damage in transit. The use of alternative packaging materials may not achieve the effect. All instrument related documentation and accessories provided by the manufacturer are retained for future use.

3.1.2 Integrity check

Check the integrity of the goods. Please check the complete documents and accessories with the instrument according to the packing list. Visually check the shipping packages, instruments and accessories for possible transportation damage. If any parts are broken, please contact the manufacturer in time.

3.2 Environment Requirement

When installing Purifier HTS, avoid placing it in the places where there is a lot of dust, vibration, strong magnetic field, direct sunlight or ultraviolet radiation, airflow, high humidity or high temperature fluctuation.

Please place the instrument on a regular experiment table to ensure that:

- The working area is flat, dry, clean and secure, with extra space for accessories, cables, etc;
- At least 10 cm of free space is provided for ventilation on the table around the instrument;
- The ambient air is clean, free from corrosive steam, smoke and dust;
- Ambient temperatures range from 5°C (41°F) to 40°C (104°F);
- Humidity is low and condensation does not occur (relative humidity is between 10% and 80%);
- Install the Purifier HTS in a protected place where no one can step on or trip over the power cord, and where it is easy to access the power cord when the plug needs to be removed;
- Care should be taken not to operate the instrument in an environment with potentially harmful liquids or gases.

3.3 Precautions

- Always ensure that the laboratory power supply voltage meets the specification on the label on the back of the instrument;
- Do not smoke or eat or drink while using this device;
- Clean hands thoroughly after handling the buffer solution;
- Follow regular laboratory procedures for handling samples that may be dangerous;• Adhere to good laboratory practices and wear appropriate protective clothing such as disposable gloves and laboratory coat;
- Ensure that the working area is well ventilated;
- Do not spill liquid inside or outside the device.



Caution Do not place the instrument near magnetic tapes, computer discs or other magnetic storage devices, such as credit cards, as they may be damaged by the strong magnetic field of the instrument magnetic head.



Warning Do not put the Purifier HTS magnetic head near the computer monitor, as this may damage the monitor.
The product has a strong permanent magnet. This product should not be used by people wearing pacemakers or metal prostheses. Prosthetic devices such as pacemakers or prostheses may be affected or damaged by close contact with strong magnetic fields.

3.4 Installation Settings

This section describes the installation Setting that must be performed prior to operating or relocating the instrument.

3.4.1 Power Connection



Warning Make sure that the power switch on the rear panel is in the "O" position. Never connect an ungrounded power outlet. Do not use any power cord other than the one provided by the manufacturer.

First connect the power cord to the power connector and insert into the instrument. Next, connect the power supply to a properly installed, well-grounded power outlet.

3.4.2 Operation Check

First turn on the instrument to "I". Instruments are initialized for testing and adjusting. The display interface is the user management interface. It is recommended that have a check, which use the maintenance program to verify proper instrument operation. If the check is correct, you can continue to run on your own.

Chapter 4 Instructions for Use

4.1 Starting

Before turning on Purifier HTS, make sure that the voltage on the label which is on the left bottom of the back panel matches the local voltage.



Warning Never operate the instrument on an ungrounded electrical outlet.

4.2 Programs

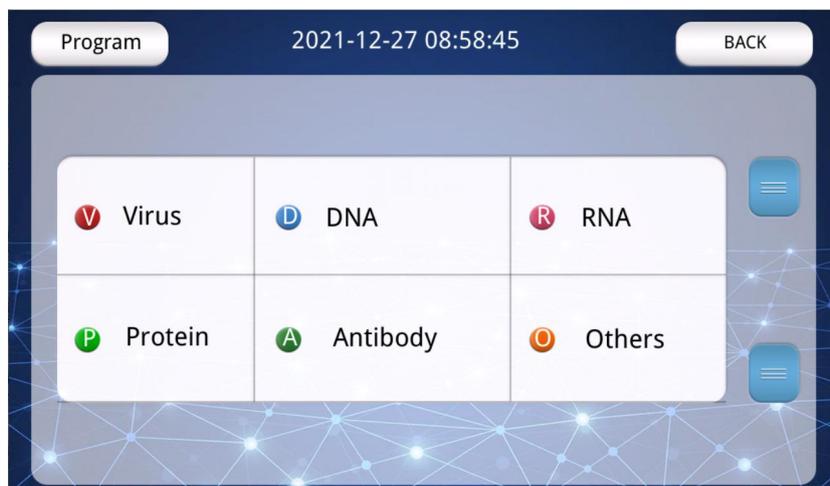
4.2.1 Home Screen



The **default program** displays a list of programs that are preset in the Purifier HTS software and cannot be edited or deleted. The **user program** is the program that the user edits and saves themselves, and the user can edit and delete the user program according to the experiment needs. **New program** can edit new programs. New programs can also be edited.  Display the current status of the instrument, “**Idle**” means the instrument is idle condition, “**Run**” indicates that the instrument is running a program, “**Check**” indicates that the instrument is in the state of power-on self-test.

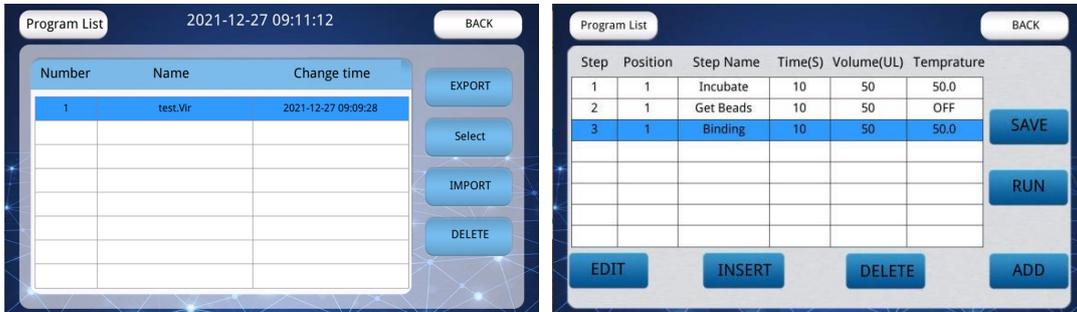
4.2.2 Program Running

Click "**User Program**" to enter the program classification interface.

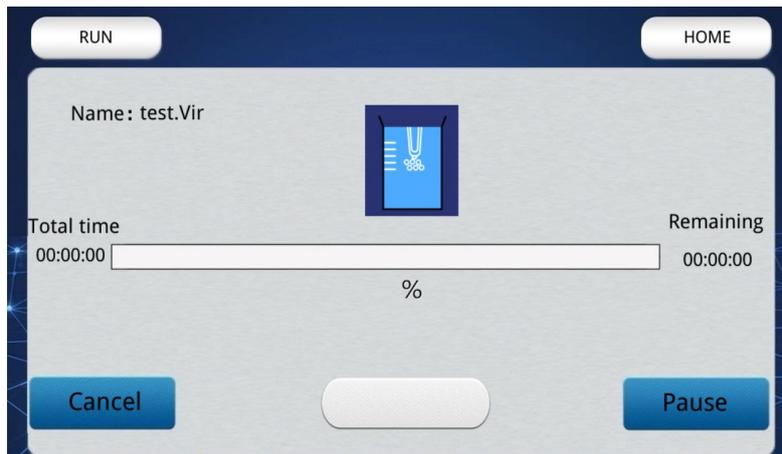


Users can select any file in the table, for example by clicking the "DNA" button to enter the list of programs. Click the program you want to run, and click "Select" to enter the program details interface.

The program detail interface displays the step number, board position number, item name, time, volume, temperature and other parameters. After confirming that the program is correct, click "Run" to run the program.



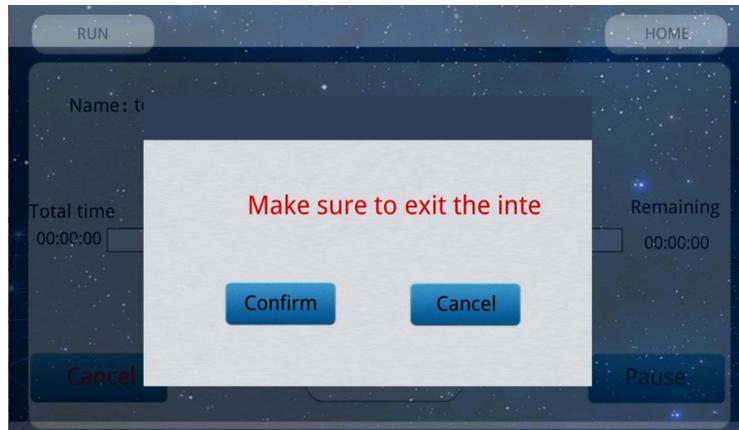
During the program running, the interface displays the total time and remaining time of the program. Click "Pause" to pause the program.



Click "Continue" to resume running.

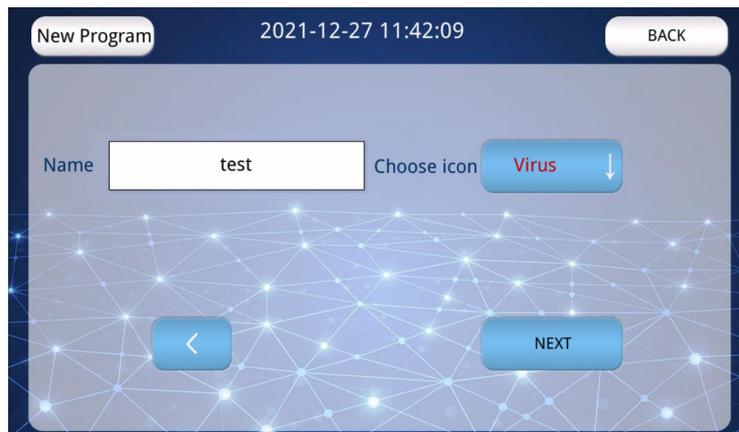


Click "**Cancel**", a dialog box will indicate whether to exit the current running program or not. Click "**Cancel**" to continue running, and click "**Confirm**" to stop running. Customers should use this function with caution.

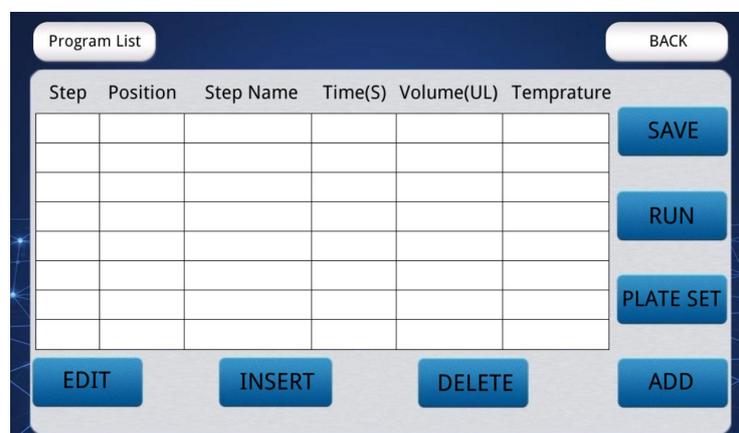


4.2.3 New Program Creation

Click "**New Program**" on the main interface to create a new programs according to the customer's requirements. Enter the program name and select the program type. Click  or "**Back**" to return to the main screen. Click "**Next**" to enter the program editing interface.



Click "**Add**" to add steps after, click "**Insert**" to add steps before the selected step, and click "**Delete**" to delete steps. Click "**Edit**" to set step parameters. Click "**Back**" to return to the main screen.



Parameters edition should be according to the actual situation to set the plate position, solution volume and step options.

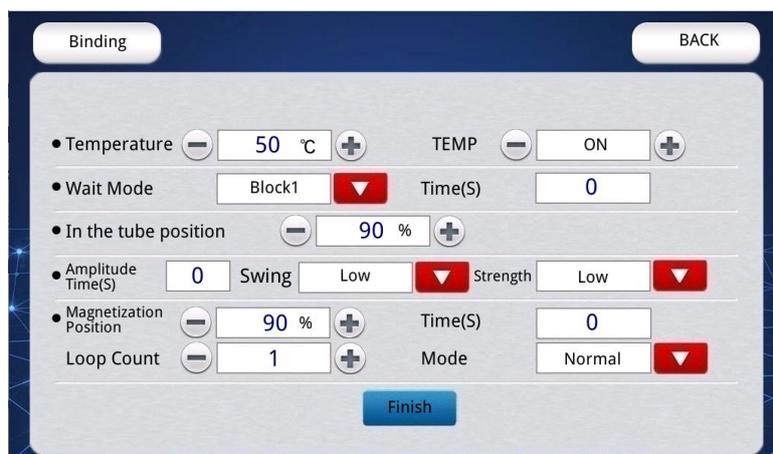


Note Purifier HTS only contains 4 plate positions, of which 1 and 4 are heating plate positions. Generally, No. 1 The plate position corresponds to the combination step, and the plate position 4 corresponds to the elution step. Please set the program steps according to the plate position.
The machine has the liquid level identification function. Please fill in the liquid volume accurately.

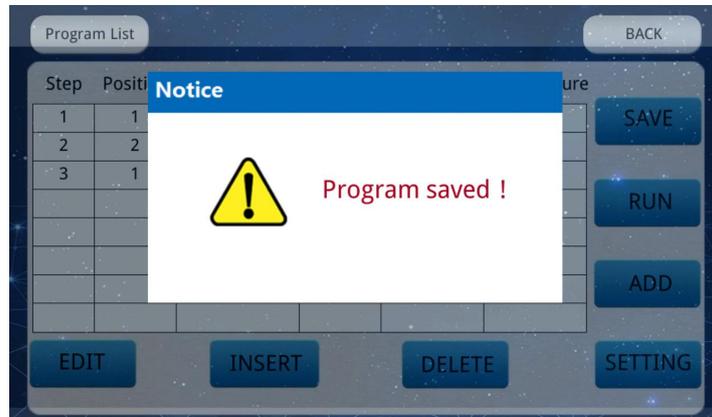
Click "next" to enter the parameter setting interface.



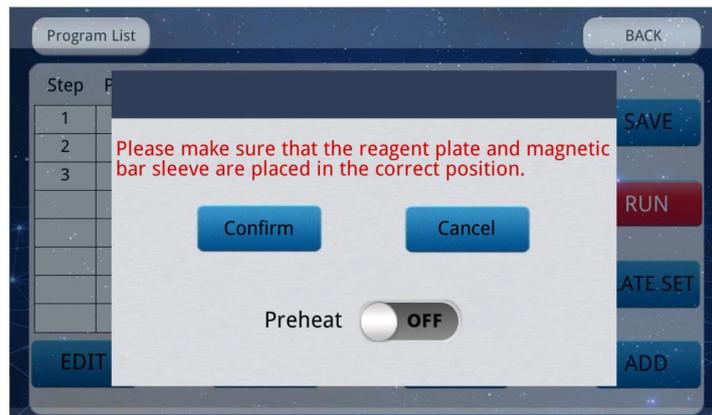
The heating temperature and time are selected according to the requirements of the experiment. The temperature setting range is 0-99°C, and the temperature can be switched. The entry position of the deep-well plate is the position where the magnetic tip comb enter the deep-well plates for mixing; 90% is recommended. High, medium and low vibration intensity are available. The magnetic absorption position is the position where the magnetic rods enters the deep-well plate for magnetic suction; 90% is recommended. There are two modes of magnetic absorption: one-step magnetic absorption and step-by-step magnetic absorption. The chosen magnetic absorption time is a cycle time, no less than 15 sec is recommended. Click "**Done**" when you're ready.



After setting the program, click "Save", and the "Program Saved" dialog box appears; the program will be saved in the folder corresponding to the user's program.



Click "run" to run the program, and a dialog box will pop up on the interface. Confirm again that the reagent plate and magnetic rod sleeve have been placed in the correct position. Click "confirm" to run the program, click "Cancel" to return to the program details, and click "pre heating switch" to turn on and off the pre heating function.



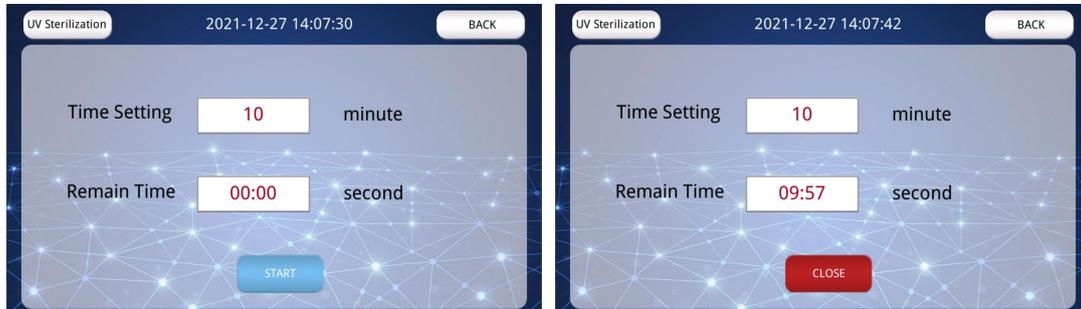
4.2.4 User Settings

The user can select "User Setting" on the main screen to set the parameters of Purifier HTS. After entering the user setting interface, the user can set the language, fan switch, light switch and prompt tone switch. There are two modes of language: Chinese and English. "Factory Setting" is not accessible to the users. if necessary, please to contact the manufacturer.



4.2.5 UV Light Settings

Click "UV Sterilization" on the main interface to set UV disinfection, and set the time in the time setting column. The remaining time is displayed as the time countdown. Click "Start" to start UV disinfection. Click "Close" to stop UV disinfection.



4.3 Shutting Down

Turn off Purifier HTS:

- (1) Press the power switch on the rear panel of the instrument to the OFF position to turn off Purifier HTS. It is recommended to turn off the instrument at night and on weekends.
- (2) Wipe the surface of the instrument with a soft cloth or paper towel with distilled water, mild detergent (SDS, sodium lauryl sulfate) or soap solution.
- (3) If contaminated reagents have been spilled on the workbench, please clean them with 75% ethanol or other disinfectants (see page 12 "Decontamination Procedure").



Warning Remove the deep-well plate and magnetic tip comb that are used in the instrument. Dispose of all deep-well plates and magnetic tip comb as biohazard waste.

4.4 Emergencies

If an abnormal situation occurs during operation, such as liquid spilling into the instrument, please follow the steps below:

- (1) Turn off the instrument immediately.
- (2) Unplug the power plug.
- (3) Implement appropriate corrective measures. But do not disassemble the instrument.
- (4) If the corrective measures taken do not help, please contact authorized technical service or your local agent.

Chapter 5 Care and Maintenance

5.1 Instrument Maintenance

In order to ensure the reliability of daily operations, please clean up the dust in time to prevent liquid leakage. Do not use abrasive cleaners, as they may damage the paint surface.

It is recommended that you clean the surface of the instrument regularly to maintain its good appearance. Wipe with a soft cloth dampened with warm water and neutral detergent. If necessary, clean the outer surface of the instrument and the turntable with clean low-pressure compressed air, or a cloth dampened with water or a mild detergent.

Although Purifier HTS is made of high-quality materials, you must remove the spilled salt solution, chemical solvent, acid or alkaline solution from the surface immediately to prevent damage to the instrument.



Caution The painted surface can be cleaned with most laboratory cleaners. Do not expose the surface to concentrated acid or ethanol for a long time to avoid damage. The display, plastic housing and surface can be cleaned with mild laboratory cleaners or alcohol.



Warning If any surface is contaminated with biologically hazardous materials, it should be cleaned immediately with a mild disinfectant solution. Do not autoclave any part of the instrument.

5.2 Cleaning

Keep the surface of the platform clean to prevent dust and dirt from entering the instrument. At least once a week, clean the surface of the turntable with a soft cloth or paper towel dampened with ethanol, mild detergent (SDS, sodium lauryl sulfate) or soap solution. If contaminated reagent is spilled out on the turntable, clean it with a cloth dampened with ethanol or mild detergent.

5.3 Magnetic Rods Cleaning

If necessary, soak the magnetic rods in alcohol, mild detergent (SDS) or soap solution, and then wipe the magnetic rods finally.

5.4 Waste disposal

Follow the specific regulations of laboratories and the country for handling biological waste. For the disposal of contaminants, please refer to the relevant local regulations.



Warning The sample may be potentially contaminated. Dispose of disposable deep-well plates, parafilm, magnetic tip comb, disposable gloves, syringes, and disposable pipette tips as biohazardous waste.

5.5 Decontamination Procedure

If you have spilled out contaminant reagents, please perform a decontamination procedure.



Warning The decontamination procedure should be carried out by authorized trained personnel in a well-ventilated room, wearing disposable gloves, protective glasses and clothing.

Follow regular laboratory procedures for decontamination. The decontamination instructions provided with the reagents used should be followed. It is strongly recommended to perform a complete decontamination procedure before transferring the instrument from one laboratory to another, or before sending it to a repair service department.

5.5.1 Decontamination Reagent Types

75% ethanol
1%-3% Virkon™ solution
4% glutaraldehyde solution
Chloramine T
Microcde SQTM 1:64
4% Decon™ 90min

5.5.2 Decontamination Procedure

- a) Wear disposable gloves to protect yourself.
- b) Prepare the cleaning agent: 200ml 4% glutaraldehyde solution (or other reagents recommended by the security officer).
- c) Empty the turntable.
- d) Turn off the power switch and disconnect the power cord.
- e) Use a cloth moistened with 75% ethanol to disinfect the outside of the instrument.
- f) Put the instrument in a big plastic bag. Make sure the front housing is open.
- g) Put a piece of cloth soaked in glutaraldehyde solution in the plastic bag. Make sure that the cloth does not touch the instrument.
- h) Seal the instrument in a plastic bag for at least 24 hours.
- i) Take the instrument out of the plastic bag.
- j) Clean the instrument with mild detergent.
- k) Use 75% ethanol to remove stains.
- l) After performing the decontamination procedure, attach a signed and dated decontamination certificate on the transport package and attach it to the outside of the package (see Appendix A: "Certificate of Decontamination").

5.6 Packaging for repair

If you need repair the instrument, please package it following the guidelines below.



Caution Before removing the instrument from the laboratory or performing any repair on it, it must be thoroughly cleaned.

When sending the instrument for repair, please remember:

- Inform the reason for repair.
- Decontaminate the instrument before hand.
- Pack the instrument according to its state before disassembly.
- Use the original packaging to ensure that the instrument will not be damaged during transportation. Any damage will incur additional service charges.
- Return the instrument (or other items) with a signed and dated decontamination certificate (see Appendix A: "Certificate of Decontamination"). And attach it to the outside of the package.
- After you contact the local agent or the manufacturer's technical service department, please specify the disfunction.
- Please refer to page 15 for more information on storage and transportation temperatures.

5.7 Service Contract

It is recommended that a service engineer trained by the manufacturer conduct a regular maintenance and repair of the instrument every 12 months. This ensures that the product is properly maintained and used without any problems.

5.8 Fill in the system log

System logs, including operation summary, maintenance procedures, error messages and other useful information about system. These is very useful for proper maintenance of the system. Please refer to Appendix B: "System Log". You can copy the form as many times as you need, but keep the original blank form in the user manual.

5.9 Disposal of the instrument

If Purifier HTS must be discarded, please follow the specific regulations of the laboratory and the country for the treatment of biological waste. The disposal of the instrument is carried out in accordance with the laws and regulations of the local authorities on the recycle of electronic equipment and waste. Disposal procedures vary from country to country. For the original packaging and packaging materials recycle, please cooperate with a recycler you are familiar with.



Warning Disinfect the instrument before disposing of it. Please refer to decontamination Procedures on page 12.

Chapter 6 Technical Parameters

6.1 General Parameters

As part of our continuous product development plan, the manufacturer reserves the right to change any parameters without prior notice.

General parameter	
	Size
Device	(510mm x 430mm x 470 mm) ±10mm
	Weiget
Device	about 27kg[±0.5kg]
Operating temperature range	+ 5°C to + 40°C
Operating humidity range	The maximum relative humidity is 80% when the temperature is lower than 31°C, and the humidity drops lineary to 50% at 40°C.
Transport condition	-40°C to +70°C, packed by transport package
Storage condition	-25°C to +50°C, packed by transport package
Main Power	100-240 Vac, 50/60 Hz
Power consumption	Maximum 96 VA
Heat dissipation	Maximum 328 BTU
Internal memory	about 500 files
File input	Use a computer or USB storage
Computer interface	RS232
General application	Run 10 times per day, run 250 days a year; 40 minutes of files use medium running speed; room temperature

6.2 Performance parameter

Performance parameter	
Processing volume	20-1000ul
Processing time	10min
Capacity	1-96
Collection efficiency of magnetic beads	≥98%
Magnetic bead size	Average diameter > 1um
Magnetic rod	96 Magnetic rod
Module station	4
Deep-well Plate type (disposable)	Micro 96 deep-well plate
Magnetic rod tip comb (disposable)	Four 96 deep-well plates with one comb
Heating temperature Accuracy of heating module	from +10°C to 105°C ±2°C
Display	10"LCD, 1024×600 pixel color display

6.3 Safety parameters

The safety parameters include the following environmental conditions, which must not exceed the regulations stated in the operating conditions

Altitude	maximum 2000m
Temperature	+5°C to 40°C
Humidity	The maximum relative humidity is 80% when the temperature is lower than 31°C, and the humidity drops linearly to 50% at 40°C
AC power fluctuation	Not more than ±10% of the marked voltage

6.4 Compliance

Purifier HTS meets the following compliance:

YY 0505-2005/IEC 60601-1-2:2001

GB 4793.1-2007/IEC 61010-2:2001

6.5 Error code

P96 error code	P96 error type	Solution
X01	X axis photoelectric switch error	If the error is reported repeatedly after restarting, contact
X02	X axis motor error	If the error is reported repeatedly after restarting, contact
Z01	Z axis photoelectric switch error	If the error is reported repeatedly after restarting, contact
Z02	Z axis motor error	If the error is reported repeatedly after restarting, contact
M01	M axis photoelectric switch error	If the error is reported repeatedly after restarting, contact
M02	M axis motor error	If the error is reported repeatedly after restarting, contact
S01	S-axis photoelectric switch error	If the error is reported repeatedly after restarting, contact
S02	S axis motor error	If the error is reported repeatedly after restarting, contact
T03	Heating detection error	If the error is reported repeatedly after restarting contact the

Chapter 7 Other information

7.1 Production Date

See the label for details.

7.2 Service life

The recommended service life should not exceed 5 years.

7.3 Components List

Purifier HTS Packing List			
Number	Item Name	Quantity	Unit
1	Purifier HTS	1	pcs
2	96 magnetic rod	1	pcs
3	Allen wrench	1	pcs
4	Screws	5	pcs
5	Power cable	1	pcs
6	Manual	1	pcs
7	Quick Operation Guide	1	pcs
8	Warranty Card	1	pcs
9	Certificate of quality	1	pcs
10	Quality inspection report	1	pcs
11	96-well plates	1	pcs
12	96 magnetic rod tip comb	1	pcs

7.4 Interpretation of Graphics

	Start		Warning for safety
	Close		Warning electric shock
	WEEE		Attention
	Warning against biohazard		

7.5 Manual revision date

2021.12.20

7.6 Target customers

This instruction is for end-users, such as scientific researchers and laboratory technicians; it provides basic information about the 96-channel automatic nucleic acid extraction and purification instrument (referred to as Purifier HTS), including the installation and operation of the instrument.

7.7 More information

For the latest information on products and services, please visit our website: <http://www.genfine.com/>. We strive to provide you with suitable and helpful documents. If you have any comments on this user manual, please tell your local agent. We will be very grateful.

7.8 Safety and User Guide

(1) To reduce the risk of injury or biohazard contamination, and to avoid fire or electric shock, always follow basic safety precautions when using Purifier HTS.

(2) Before operating the instrument, please read this instruction manual completely. Failure to read, understand or follow this manual may cause damage to the instrument and laboratory, injury to the operator, or poor performance of the instrument.

(3) Comply with all "Warning", "Caution" statements, safety symbols and markings on the instrument and documentation.

(4) This equipment can only be operated with specially designed software.

(5) Do not force the microplate onto the turntable.

(6) Purifier HTS is for laboratory research use only. Please comply with appropriate laboratory safety precautions, such as wearing protective clothing and following certified laboratory safety procedures.

(7) Strictly follow the preventive maintenance instructions to keep the instrument in its best condition and ensure maximum reliability. Poorly maintained instruments may cause abnormal test results.



Warning This product contains strong permanent magnets. People who wear pacemakers or metal prostheses should not use this product. If the pacemaker or prosthesis comes into close contact with a strong magnetic field, it may be affected or damaged.



Chapter 8 Manufacturer and Medical Device Information

Manufacturer: GENFINE BIOTECH (CHANGZHOU) CO., LTD.

Medical device production record number: NMPA Reg. No.: 20220032

Manufacturer Address: Building E4, Changyang Road, West Taihu
Technology

Industrial Park, Changzhou City, Jiangsu Province

Contact: 0519-83761557

Chapter 9 Order Information

If you need to order, please contact your local agent for ordering and service information. The ordering information codes are shown in Table 9-1 to Table 9-2 below.

9.1 Purifier HTS configuration

Table 9-1 Product Item List

Item No.	Device/System
P96S-B01-01	Purifier HTS (Chinese version)
P96S-B01-02	Purifier HTS (English version)
P96S-B01-03	Purifier HTS (Custom version)

9.2 List of accessories and consumables

Table 9-2 List of accessories and consumables used with Purifier HTS

Content	PS
Purifier 96 magnetic tip comb	96 channel
96-well plate	96 channel
Purifier 96 magnetic rod	96 channel

Appendix A: Certificate of Decontamination

Name: _____

Address: _____

Telephone / Fax: _____

Device: _____ Record Number: _____

A) I confirm that the returned items are not contaminated with liquid, toxic, carcinogenic or radioactive substances or any other harmful substances.

B) I confirm that the returned items have been decontaminated and can be processed without affecting the health of the personnel.

Materials used: _____

Contamination specific information: _____

Decontamination procedure¹: _____

Date and place: _____

Signature: _____

Name (Capital) : _____

*When the device is used with radioactive materials, the signature of a radiation safety officer is also required.

This device has been certified by the following signatory to be free of radioactive contamination.

Date and place: _____

S i g n a t u r e :

_____ Name (Capi

tal) : _____

This page can be copied.

¹ Including the decontamination reagent used.

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marketing@genfine.com