

# **Nucleic Acid Extractor**

# **User Manual**

(REV: 1.0)





### **Note**

Thanks for using TS-32 Nucleic Acid Extractor, which will be described as Nucleic Acid Extractor.

Please read this instruction carefully before using, in order to make sure that use it properly.

Please keep the instruction properly after use.

Product Name: Nucleic Acid Extractor

Trade Name: Nucleic Acid Extractor

Model Number: TS-32

Manufacturer: TransGen Biotech Co., Ltd.

Address: Building No.4, Zhongguancun Dongsheng International Science Park,

No. 1 North Yongtaizhuang Road, Haidian District, Beijing, China 100192

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Service life: 8 years

### Information of user manual

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# Copyright

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No one shall take photographs, copy, or translate all or part of this manual into other languages.



### **Statement**

TRANSGEN has the right of final interpretation of this statement:

- Only when all the following requirements are met can the company consider itself responsible for the safety, reliability and performance of the product.
- Assembly operations, expansion, adjustment, improvement and repairing should be appointed by TRANSGEN and distributors.
- All spare parts, accessories and consumables are supplied by TRANSGEN or any alternatives are approved by the TRANSGEN.
- Relevant electrical equipment should meet the national standards and the requirements of this instruction.
- All operations should follow the instruction.

### **Maintenance and Service**

The products purchased are guaranteed free of charge for one year from the date of installation. However, the damage caused by the following circumstances is not included in the free maintenance:

- The use environment does not meet the specifications.
- Damage caused by failure of use specified power supply or abnormal power supply;
- Man-made damage;
- Damage caused by maintenance by unauthorized personnel of manufacturer





■ Damage caused by other irresistible natural factors, such as earthquakes, fires, wars, etc.

Any questions users may contact the distributor or manufacturer at any time according to the following contact information, After the expiration of the warranty period, the company can continue to provide paid maintenance services.

## After-sales service unit

Name: TRANSGEN BIOTECH CO., LTD.

ADD: Building No.4, Zhongguancun Dongsheng International Science
Park, No. 1 North Yongtaizhuang Road, Haidian District, Beijing,
P.R.China

TEL: +86-400-8980321

Email: <a href="mailto:info@transgenbiotech.com">info@transgenbiotech.com</a>

Website: <a href="https://www.transgenbiotech.com">https://www.transgenbiotech.com</a>



- This instrument is only allowed to operate by TRANSGEN staff or the one who is appointed by distributor.
- Please use the extractor under the condition that the instruction required. If the operation conditions violate the instruction, the extractor may not work properly, the measurement results are unreliable, the extractor components may be damaged and personal safety may be harmed.





# **Table of Contents**

Tab	le of C	ontents	5
Chapter	1.	Summary	7
1.1	Sur	mmary	7
1.2	App	olication Range	7
1.3	Syr	mbol Description	8
Chapter	2.	Instrument Introduction	1
2.1	Sur	mmary 1	1
2.2	App	olication Range	1
2.3	Prir	nciple 11	1
2.4	Coi	mposition of product structure	1
	2.4.1	Display screen	4
	2.4.2	Front door	4
	2.4.3	Instrument interface	4
	2.4.4	Power switch	4
	2.4.5	Reagent& sample processing chamber	4
2.5	Per	formance indicators	6
2.6	Env	vironment test	6
2.7	Ele	ctrical Safety	6
2.8	Ele	ctromagnetic compatibility	7
2.9	Pro	tection level	
Chapter		Installation instructions	
3.1		ckage Inspection18	
3.2	-	ening machine package Inspection $\dots \dots 18$	
3.3		move transport fixed screws	
3.4		ecifications and Environment Requirements	
3.5		tallation Requirement20	
3.6	•	ace Requirement	
3.7	Coı	nnect Power supply	
Chapter		Operational Instruction	
4.1		itch on extractor	
	4.1.1	Start-up	
	4.1.2	Self-check	
	4.1.3	UV Disinfection	
4.2		nning machine	
		Select program	
		Running status	
4.3		ogram	
	4.3.1	Edit the program	
	4.3.2	Parameters setting	7



4.4	UV sterilization	27
4.	.4.1 Sterilization time	27
4.	.4.2 Sterilization status	28
4.5	Setting	
4.	.5.1 System setting	28
4.	.5.2 Upgrade	29
4.6	About	
Chapter5.	User Services	
5.1.	User Maintenance	
5.2.	Software upgrade	
5.	.2.1 U disk upgrading	
5.	.2.2 TF upgrade	
Chapter6.	Trouble Shoot	
6.1.	Summary	
6.2.	Trouble Information and Solution	
Chapter7.	Maintenance	
7. 1.	Inspection	
7.2.	Maintenance Plan	
7.3.	View Information	
Chapter8	Accessory information	39



# Chapter1. Summary

# 1.1 Summary

This chapter described how to use this user manual. The installation, use and maintenance of TS-32 are described in detail in this user manual. Before using the TS-32, please read and understand this instruction carefully to ensure the proper use of the extractor, its best performance and operator safety.



Please follow the instructions strictly.

# 1.2 Application Range

This instruction is applicable to medical laboratory professionals or trained doctors, nurses and experimenters:

- Get knowledge of TS-32 hardware and software;
- Daily sample extraction;
- Operating system maintenance and trouble shooting.





# 1.3 Symbol Description

The following symbols are used in this instruction. The meanings of each symbol are explained as follows:

symbols	Meaning
٨	This symbol is warning the operation should
/!\warning	be according to the instruction, otherwise it
ZVVARNING	may cause personal injury.
	This symbol is warning the operation should
$\wedge$	be according to the instruction, Otherwise it
∠!\CAUTION	may Cause product failure, damage or affect
	test results.
	This symbol is warning the operation should
$\wedge$	be according to the instruction, and give
∠!\NOTE	notice of important information in the
	operation steps.
	This symbol is warning the operation should
	be according to the instruction, otherwise it
•	may cause biohazard.

You may see the symbols on extractor:

Symbol	Meaning
$\triangle$	Warning sign
	Biohazard



	<del></del>
	UV lamp warning sign
	Hight temperature warning
	Manufacturer
	Date of Manufacture
SN	Serial Number
IVD	Use for In Vitro Diagnostic
	Use-by date
EC REP	Authorized representative in the European Community
(€	The symbol indicates that the device complies with the European Council Directive 98/79/EEC concerning medical devices.
+55°C	Temperature limit
	Waste equipment should be recycled in accordance with local regulations



50kPa	Atmospheric pressure limitation
0%93%	Humidity limitation
<u>†</u>	Upward
	Fragile, handle with care
	Keep away from rain
3	Stacking limit by number
	Recycle
20)	Pollution identification of electronic information products

All labellings in this instruction are for illustration only, not for other purposes.



# **Chapter2.** Instrument Introduction

### 2.1 Summary

TS-32 Nucleic Acid Extractor are in vitro diagnostic devices that are used with relative reagents to extract and purify nucleic acid from samples for nucleic acid detection.

# 2.2 Application Range



- This device is used for sample pre-processing.
- The instrument can be reused, and the nucleic acid extraction reagent is disposable.
- This device is Class B product (suitable for household environment).

This extractor is used to extract and purify nucleic acids from human samples.

# 2.3 Principle

Mix the sample with lysis solution in the kit and placed in the instrument together with the (stirrer) and other reagents kit. The stirrer (magnetic rod sleeve) is automatically moved by the instrument to transfer the magnetic beads in each reagent for nucleic acid lysis, washing and elution. Finally, nucleic acid products are obtained and nucleic acid extraction is completed.

# 2.4 Composition of product structure

The extractor is mainly composed of mechanical parts and electrical parts.





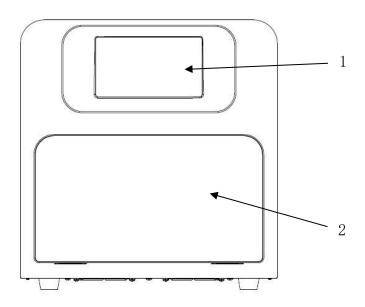


Figure 2- 1 Front view

1—display screen 2—Front door

4

Figure 2- 2 Back view

1——Power switch 2——Power connector 3——USBport 4——Rear fan cover 5——Bottom fan cover



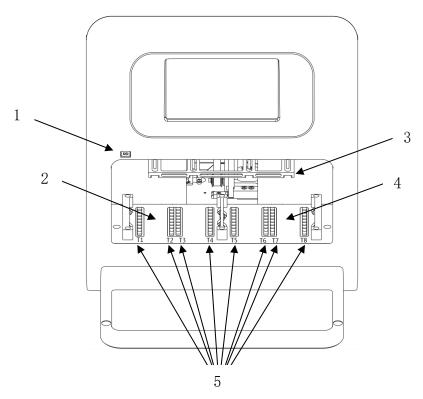


Figure 2-3 door open showing

- -Door opening detection sensor -Plate holder (left)
- -Stirrer (magnetic rod sleeve)bracket
- -Heating block(T1~T8)

- -plate holder (right)

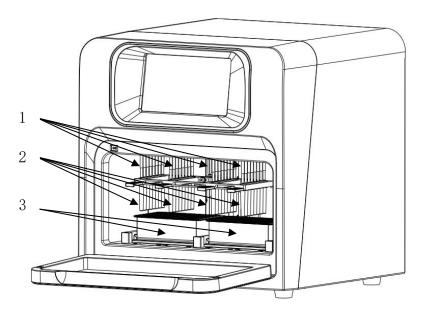


Figure 2- 4 Reagent loading diagram

-Magnetic rod -Stirrer(magnetic rod sleeve)

-Reagent kit plate(extraction platform)





### 2.4.1 Display screen

The display screen is a touch LCD screen. All operations of the instrument are operated through the touch screen. With the prompt of the interface, the user can click manually to complete the required function.

#### 2.4.2 Front door

The front door is on front of the machine, The upper left corner of the door is the door opening detection sensor. After the door is opened, reagent kits and stirrer (magnetic rod sleeve) can be placed.



The door must be kept closed to run the nucleic acid extraction program,
 otherwise the extractor cannot operate normally.

#### 2.4.3 Instrument interface

- Power interface: AC power interface
  The power interface is located at the back of the extractor and is used to connect to the normal power.
- USB interface: standard USB 2.0 interface

  USB interface is located at the back of the extractor, which is used to connect U disk to upgrade the software program of the main control board.

#### 2.4.4 Power switch

The power switch is located at the back of the extractor to turn on and off the power required by the extractor.

# 2.4.5 Reagent& sample processing chamber

The reagent plate holder (extracting platform) is located at front of the extractor, which is the core area of nucleic acid extraction. The stirrer (magnetic rod sleeve) and the reagent kit are fixed at a specific position. Through the combination of the magnetic rod and the stirrer (magnetic rod sleeve), the





nucleic acid lysis, adsorption, cleaning, elution and other extraction processes are completed.

- Stirrer(magnetic rod sleeve): it is a plastic 8-row round sleeve, which is used to separate the magnetic bar from the magnetic beads in the reagent and facilitate the separation of the magnetic beads. It is a disposable consumable. When in use, the magnetic rods are inserted into the stirrer (magnetic rod sleeve) bracket along the horizontal groove.
- Reagent kit: The 96-well kit made of plastic is used to lysis, washing, elution and purify nucleic acids. It is a disposable consumable. The inside of the kit is pre-installed with lysis solution, washing solution, magnetic bead solution, eluent, and it is sealed with aluminum foil. The aluminum foil needs to be torn off when using, and the sample is added to the lysis solution, and then placed on the plate holder of the extractor, The stirrer (magnetic rod sleeve) and the reagent plate need to be used together. When placing a reagent plate, insert two stirrers at the corresponding position above it; when placing two reagent plates, insert four stirrers above it.



- Place the kit order: Place the kit plate first, then insert the stirrer(magnetic rod sleeve).
- Take-out sequence: Take out the stirrer (magnetic rod sleeve) first then take the kit plate out.
- The reagents should be used in conjunction with the kits designated by TRANSGEN. For the use of reagents, please refer to the kit instructions for details.
- There are a total of 8 heating blocks from T1 to T8 on the kit platform,
   so you should prevent burns during the use of the instrument.



#### 2.5 Performance indicators

- Extraction time: 9-30min
- Sample type: Serum, Plasma, Whole blood, Oral swabs, Sputum,
   Feces, etc.
- Processing volume: Sample volume: 20uL~1000uL, Elution volume:
   50uL~100uL
- Purification repeatability: CV≤5%
- Extraction sensitivity: Detection rate of 100 copies/ml positive samples
   is ≥95%
- Temperature range: Lysis temperature: room temperature~105℃,
   Elution temperature: Room temperature~105℃
- Temperature accuracy: ±5<sup>°</sup>C
- Motion accuracy: ≤0.1mm
- Reagent type: Pre-packaged reagents
- Operation interface: 7 inch touch screen
- Disinfection and sterilization: UV sterilization

#### 2.6 Environment test

- a) The climatic and environmental test meets the requirements of group I of the climatic and environmental test in GB/T 14710-2009.
- b) Mechanical environment test complies with the requirements of MECHANICAL environment test Group I in GB/T 14710-2009.

# 2.7 Electrical Safety

It should meet the requirements of applicable clauses in IEC61010-1:2010+A1:2016/EN61010-1:2010/A1:2017, IEC61010-2-101:2015/EN61010-2-101-2017, EN61010-2-010:2014.





# 2.8 Electromagnetic compatibility

It should meet the requirements of IEC 61326-1:2012/EN 61326-1:2013, IEC 61326-2-6:2012/EN 61326-2-6:2013.

### 2.9 Protection level

According to the measurement, control and laboratory use electrical equipment safety requirements classification, extraction apparatus belongs to anti-shock Class I, overvoltage category Class II, and degree 2 of the pollution.



# Chapter3. Installation instructions

### 3.1 Package Inspection

TS-32 extractor has been inspected strictly before delivering and packaged properly to ensure that it is free from impact during transportation.

Please check carefully whether there are the following damages in the outer packing before open the box:

- Deformation
- Obvious water immersion
- Obvious impact
- Sign of being open

Once the above damage is found, please inform TRANSGEN or local distributor immediately before opening the box.

### 3.2 Opening machine package Inspection

Please check the items in the box according with the packing list, if found there is missing or damaged, contact manufacturer or local distributor.

After checking correctly, remove the extractor from the packing box and place it on a fixed horizontal table. Please take care to handle it lightly. After the installation of the machine, please fill in the after-sale warranty card and send the scanned pieces or photos of the after-sale warranty card to TRANSGEN (custserv@transgenbiotech.com) to establish the customer files. TRANSGEN will build the customer files. After that, the product information and software upgrade services will be sent regularly, and the warranty period will be calculated from the date of installation of the extractor.





## 3.3 Remove transport fixed screws

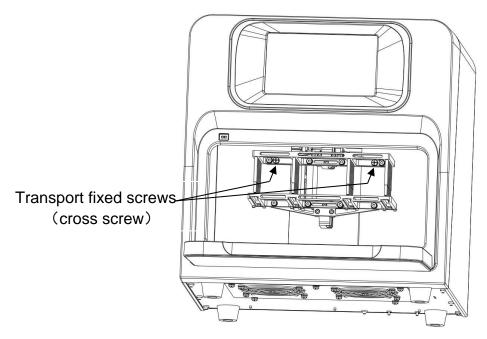


Figure 3-1 Transport fixed screws

After unpacking, remove the tape from the door, open the door, and use the screwdriver in the factory accessories to remove the transport fixing screws in the reagent compartment.



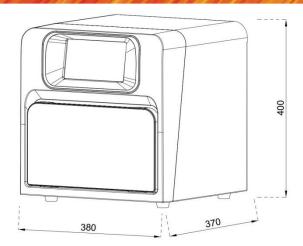
- The two transport screws must be removed before it is used for the first time, otherwise it will damage the instrument.
- Keep the transport screw in case the extractor fails, requiring it to be ship to repaired later.
- Keep the boxes and packing materials handy for later transportation or storage.
- It has to follow the local regulations or hospital waste disposal rules when disposing of packaging material.

# 3.4 Specifications and Environment Requirements

■ Dimension: WxLxH=380x370x400 (mm)







■ Weight: 23kg

■ Power supply requirement: AC 100V-240V~, 50/60Hz

■ Power: 500VA

■ Working environment temperature: 10~35°C

■ Humidity of working environment: 30%~85%

- Working atmospheric pressure range: 70kPa~106kPa( Elevation 100m~3000m)
- Storage/transportation temperature: -10~55°C
- Storage/transportation humidity: 0%~93%
- Storage/transportation atmospheric pressure range: 50kPa~106kPa
- Running noise dB:<65dB</p>

# 3.5 Installation Requirement



- The copyright of the extractor software shall be owned by TRANSGEN.
   Without permission, no organization or individual may tamper with, copy or exchange by any means or form.
- All analog and digital devices are connected to the extractor must be certified by specified IEC standards certificate (such as IEC 60950 Safety of Information Technology Equipment and IEC61010-1 Safety of medical electrical equipment). The personnel who connect the





additional equipment to the input and output signal ports is responsible for whether the system complies with IEC 61010-1 standard.

- When the extractor is connected with other electrical equipment and have a specific functional combination, and if the specifications of the equipment cannot determine whether the combination is dangerous, please contact TRANSGEN or hospital experts to ensure that the all equipment in the combination is not damaged.
- The instrument can only be used in the environment where the voltage fluctuation of the power grid is not more than 10%.

### 3.6 Space Requirement

In order to ensure the space requirement for instrument maintenance, repair and heat dissipation during working, the installation position of the extractor should meet the following demand:

- The distance from the wall or other medical devices≥10cm;
- It needs to be installed horizontal.



- In order to be free from danger, do not use the extractor in flammable and explosive environment.
- If the extractor is put into use, the device needs to be moved again to change its location or transported again for processing (when moving from one environment to another). Please refer to the storage and transportation conditions of the equipment, handle the equipment carefully and place the equipment in accordance with the space requirements mentioned above.
- Power safety: do not place the extractor in a position where it is difficult to cut off the power.





# 3.7 Connect Power supply

Insert the power socket at the back of the extractor (as shown below), and then insert the AC connector of the power cord into the power socket which should be well grounding.

# WARNING

- In order to prevent voltage surge or sag, please do not share the same socket with other high-power equipment. If sharing the same socket, please use a power surge protector which is suitable for computer use.
- The specified power cord used only and cannot be replaced or disassembled.

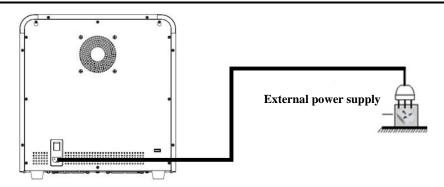


Figure 3-2 power connecting



# **Chapter4.** Operational Instruction

### 4.1 Switch on extractor

### 4.1.1 Start-up

Press the power button at the back of the extractor to turn on the instrument, the extractor is started, then confirms that the fan is running, and the screen displays the boot-up interface as following figure 4-1:



Figure 4-1 Startup interface

### 4.1.2 Self-check

During the start-up of the extractor, the instrument will conduct self-check. The screen displays the following figure 4-2:





Figure 4-2 Startup self-check

#### 4.1.3 UV Disinfection

After self-check, the instrument automatically turns on the ultraviolet lamp for disinfection, and the interface displays as follows:



Figure 4-3 UV Sterilization interface



- The normal sterilizing time is 30 minutes and can be set in the setting interface. In the process of starting up sterilizing, users can choose to skip it according to their needs to end ultraviolet sterilizing.
- When UV lamp is on for disinfection, do not manually open the front door to avoid the light radiation of UV lamp.
- There is warning mark of ultraviolet lamp.

After sterilizing or skipping the sterilizing process, it will automatically enter the main interface, and shown as below figure 4-4:





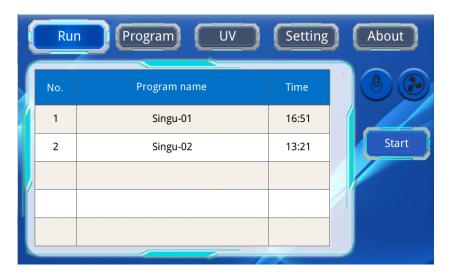


Figure 4-4 Main interface



 The display screen of the extractor is a touch screen, and all the buttons can be directly clicked on the screen for operation.

# 4.2 Running machine

# 4.2.1. Select program

Swicth on the machine, and click "Run" button, enter the running interface, the interface shown as below figure 4-5:

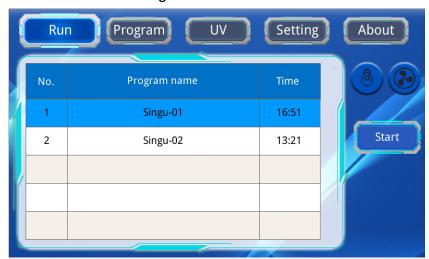


Figure 4-5 Run-select program



### 4.2.2. Running status

Click the touch screen and select the program, then click "Start" button to run the program, the enter the interface below figure 4-6:



Figure 4-6 Run- running status

### 4.3 Program

### 4.3.1 Edit the program

Click the "Program" button, enter the program setting interface, select the relative program to edit, as the below figure 4-7:

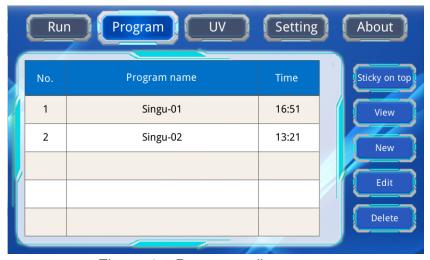


Figure 4-7 Program-edit program

Click any button of "New" / "Edit" / "Delete", enter the interface for input the password. When the right password is entered, the executing is successful. The figure is showing as follow:







Figure 4-8 Program-input password



Password is "323232".

### 4.3.2 Parameters setting

Select the program, click "Edit" button, enter the parameters setting interface as showing figure 4-9.

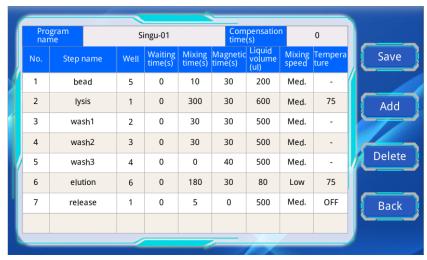


Figure 4-9 Program- parameters setting

### 4.4 UV sterilization

### 4.4.1 Sterilization time

Click "UV" button, enter the sterilization time setting interface, the UV sterilization time can be set with needs, as the figure 4-10:







Figure 4-10 UV sterilization-sterilization time

### 4.4.2 Sterilization status

After setting the sterilization time, click "Start" button, it enter the sterilization interface automatically, showing as figure 4-11:



Figure 4-11 UV Sterilization- sterilization status

# 4.5 Setting

# 4.5.1 System setting

Click "Setting" button, enter the interface of the system setting, in this interface, it can set language, touch screen sound, system warning tone and display brightness, showing as figure 4-12:







Figure 4-12 system setting interface

### 4.5.2 Upgrade

In the system setting interface, click "Upgrade" button, enter the software upgrading interface. Copy the software with the U disk, insert the U disk to the USB port on the rear of machine. When the machine detect the upgrading software, it will run the upgrading procedure automatically as figure 4-13:



Figure 4-13 Setting-software upgrading



- U disk should be FAT32 format, the upgrading software should be copy to directory TS-32.
- Do not power off the instrument or remove the USB flash drive.
- The machine will automatically restart after software upgrading.





• Display software upgrade method: To upgrade the display software, power off the device, remove the back shell and insert the TF card with the upgrade file into the corresponding slot on the display, power on the device, wait for the upgrade to complete, power off the device, and remove the TF card. The software upgrade of the display screen must be carried out by professional inspectors and experiment operators trained by the manufacturer.

#### 4.6 About

Click "About" button, it enter the about display screen, the information of machine name, model, software version and manufacturer display on the interface, showing as figure 4-14:



Figure 4-14 About



# Chapter5. User Services

### 5.1.User Maintenance

In order to ensure the accurate and effective operation of the extractor, the operator should maintain the extractor regularly. Daily maintenance of the instrument is relatively easy. The relevant tools and consumables include white cotton gauze or degreased cotton, a relatively dull pair of tweezers, and 75% alcohol. When the instrument is not in use for a long time, please remove the plug and cover the instrument with dust cover to prevent dust from entering.

- Daily Maintenance: Wipe the reagent compartment of the extractor by a soft cloth with 75% alcohol.
- Once a week: Scrub the outer surface and the touch screen of the extractor by a soft cloth with 75% alcohol.
- Half a year: Clean the dust on the fan cover at the bottom and back of the instrument.



- Improper maintenance may cause damage to the extractor. Operators must follow the instructions for maintenance.
- In case of any problem not specified in the manual, please contact the customer service of TRANSGEN, and the professional personnel designated by TRANSGEN will give the maintenance suggestions.



Be sure to disconnect the extractor from the power supply during cleaning!







- All the surface parts of the extractor are potentially biological contagiousness, and safety measures should be taken during operation and maintenance.
- If samples are sprinkled on the surface of the instrument during the operation, they can be wiped with disinfected alcohol. Safety precautions should be taken in the cleaning process, and the safety operation standards of laboratories should be strictly followed.

### 5.2. Software upgrade

According to the feedback of the market and customers and the continuous upgrading of the technology, the company will optimize the software of the extractor from time to time to ensure that users can get the experience of "faster extraction, better performance and more convenient operation". When the updated version is needed, the after-sales service staff of the company will contact users in time to upgrade through flash disk or TF card.



 It is recommended to use the special flash disk or TF card provided by the manufacturer for software update to prevent infection of virus in the extractor system.

# 5.2.1 U disk upgrading

It is recommended to use the special U flash disk provided by the manufacturer to upgrade software, please follow the 4.5.2 procedure to upgrade the software.



 Please upgrade the software according to manufacturer informing, do not power off the machine during the upgrading.





## 5.2.2 TF upgrade

It is recommended to use the special TF flash disk provided by the manufacturer to upgrade software, please follow the 4.5.2 procedure to upgrade the software.



- It needs to remove machine cover of the machine; The operation shall be performed by professional inspection personnel and experimental operators trained by the manufacturer.
- During the upgrading, please do not power off the machine.





# **Chapter6.** Trouble Shoot

### 6.1.Summary

This chapter introduces the possible faults of the extractor and provides the trouble shooting method.



• This manual is not service manual. It only provides the measures that the operator should take when the extraction device fails to alarm.



 Samples and reagents are potentially dangerous for biological contagion. When operating, please observe the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.)

### 6.2. Trouble Information and Solution

It provides reference suggestions and basic solutions to problems that may be encountered. If these solutions can't solve your problem, please contact TRANSGEN Customer Service or local distributor.

No.	Description	Possible Causes	Suggestion
	Extractor cannot start, self-check failed	Power system	1) Check Power supply
1,		damage;	system, including power
		Poor contact of power	cables and power
		supply system;	sockets.
		Main control board	2) Restart instrument
		failure.	





2、	It shows that the display communication failed!	Display failure; Poor connection of the cable; Main control board failure	<ol> <li>After checking the display screen, main control board and their connecting wires;</li> <li>restart the machine</li> </ol>
3、	"Failed to reset the horizontal motor!"	The horizontal motor is malfunctioning; Horizontal optocoupler failure; Motion stuck.	1) Check the movement mechanism including motor, horizontal optocoupler and confirming that it is not stuck or failure; 2) restart the machine
4、	"Magnetic stirrer (magnetic rod sleeve)motor reset failed! "	Magnet motor is malfunctioning; Magnetic stirrer (magnetic rod sleeve)optocoupler failure; Motion stuck	1) Check the movement mechanism including motor, horizontal optocoupler and confirming that it is not stuck or failure;  2) restart the machine
5、	"Magnet rod motor reset failed!"	Magnet motor is malfunctioning; Magnetic rodoptocoupler failure; Motion stuck	1) Check the movement mechanism including motor, horizontal optocoupler and confirming that it is not stuck or failure; 2) restart the machine
6、	"Temperature sensor failure! "	Temperature sensor failure	restart the machine



# Chapter7. Maintenance



- The hospital or medical institution that uses the extractor shall establish
  a complete maintenance plan, otherwise it may cause the failure or
  unexpected consequences of the extractor and endanger personal
  safety.
- Safety inspection or maintenance of all dismantling equipment should be carried out by professional maintenance personnel. The operation of non-professional personnel may cause the failure of extractor and may endanger personal.
- Make sure the product is power-off before maintenance.
- Maintenance personnel must wear gloves and take good safety precautions.
- If there is any problem with the extractor, please contact the maintenance staff or our company.

# 7.1.Inspection

Before use the extractor, after 12 months of continuous use, after maintenance or upgrading, a comprehensive inspection shall be conducted by qualified maintenance personnel to ensure the normal operation and work of the extractor.

Inspection items should include:

- Environment and power supply requirement.
- There is no mechanical damage to the extractor.
- Power cord has no wear and good insulation.
- Use the specified spare parts
- The extraction test function is in good working condition.





If any damage or abnormal phenomenon is found, please do not use the extractor and contact the medical engineer of the hospital or the maintenance personnel of the factory immediately.

The maintenance work is completed to ensure that the product is in good working condition.

Refer to the product maintenance manual for details on how to maintain operation.

#### 7.2. Maintenance Plan

The following tasks, except visual inspection and package opening inspection, can only be accomplished by professional maintenance personnel appointed by the TRANSGEN. If you need the following maintenance, please contact the maintenance personnel in time. Before inspection or maintenance, the extractor must be cleaned and disinfected.

Inspection/Maintenance	Recommended Frequency	
Item		
Visual inspection and	1.First installation, or after each reinstallation;	
package opening	2. After each maintenance or replacement of spare	
inspection	parts	
The performance test	1.When the user suspects that the extraction is	
	inaccurate;	
	2.After the equipment parts are repaired or	
	replaced.	
	3.At least once a year.	
Position calibration	1.After the equipment parts are repaired or	
	replaced;	
	2.At least once a year.	



# 7.3. View Information

Enter the Settings on the main interface of extractor, and you can view the product information and software version information of extractor.



# Chapter8. Accessory information

Please check the contents according to the packing list after unpacking. Besides the main unit, the following accessory should be included.

- User manual
- Power cord
- Certificate of qualification
- Warranty card
- Brief Operation guide
- Certificate of Analysis
- Acceptance signature certificate

The power cord and adapter must be designated by TRANSGEN and cannot be replaced or disassembled by user themselves. If the power cord and adapter are damaged or damaged, please contact the company's maintenance personnel in time.