

Sanity 2.0 System

User Manual A/3

(Applicable to Sanity 2.0)



Contents

CONTENTS	I
PREFACE.....	III
COPYRIGHT AND DISCLAIMER.....	III
INTENDED USE.....	III
PRODUCT INFORMATION	III
Product name.....	iii
Product model	iii
Contraindications	iii
Product serial number and production date	iv
Service life.....	iv
HARDWARE CONFIGURATION	IV
SOFTWARE ENVIRONMENT.....	IV
NETWORK CONDITIONS	IV
DATA AND EQUIPMENT (SYSTEM) INTERFACE.....	IV
USER ACCESS CONTROL MECHANISM.....	IV
SYMBOL DESCRIPTION	IV
CHAPTER I SAFETY INSTRUCTIONS	1
1.1 INSTRUMENT SAFETY	1
1.2 PERSONAL SAFETY	1
1.3 BIOLOGICAL HAZARDS	2
1.4 ELECTRICAL SAFETY	2
1.5 ELECTROMAGNETIC COMPATIBILITY.....	3
1.6 OTHERS	3
CHAPTER II OPERATION PRINCIPLE	4
2.1 SYSTEM OPERATION OVERVIEW	4
2.2 SYSTEM OPERATION PRINCIPLE.....	4
CHAPTER III INSTRUMENT DESCRIPTION.....	5
3.1 MAIN COMPONENTS OF THE INSTRUMENT	5
3.2 MAIN STRUCTURE	5
3.3 PRODUCT OVERVIEW	6
3.4 INSTRUMENT PERFORMANCE.....	7
3.5 OPERATION ENVIRONMENT.....	8
CHAPTER IV INSTRUMENT INSTALLATION.....	9
4.1 TRANSPORTATION AND STORAGE.....	9
4.2 UNPACKING.....	9
4.2.1 Unpacking instructions.....	9

4.2.2	Fixing block disassembly and installation.....	9
4.3	PACKING LIST	11
4.4	INSPECTION BEFORE THE FIRST RUN	11
CHAPTER V OPERATION INSTRUCTIONS.....		12
5.1	TYPICAL OPERATION PROCESS	12
5.2	START TESTING	12
5.2.1	Start the instrument	12
5.2.2	Create the test	13
5.2.3	Scan the kit information	13
5.2.4	Scan the sample information	13
5.2.5	Add the sample.....	13
5.2.6	Place the kit	13
5.2.7	Scan the operator information	13
5.2.8	Set automatic shutdown (optional).....	14
5.2.9	Start the test.....	14
5.2.10	Complete the test.....	15
5.2.11	Report viewing and retrieval	15
5.3	UV LAMP DISINFECTION	16
5.4	INSTRUMENT INFORMATION.....	16
5.5	SYSTEM SHUTDOWN	16
5.6	DEVELOPMENT OPTIONS.....	17
CHAPTER VI MAINTENANCE.....		19
6.1	MAINTENANCE REQUIREMENTS.....	19
6.2	WASTE DISPOSAL	19
6.3	INSTRUMENT CLEANING	19
6.3.1	Clean the shell of instrument.....	20
6.3.2	Clean the touch screen.....	20
6.3.3	Clean the carrier	20
6.4	UV DISINFECTION.....	20
6.5	DESCRIPTION OF CONSUMABLES	20
CHAPTER VII PACKING AND SHIPPING.....		21
7.1	PACKING STEPS	21
CHAPTER VIII CALIBRATION AND QUALITY CONTROL		23
8.1	CALIBRATION	23
8.2	QUALITY CONTROL.....	23
APPENDIX I TROUBLESHOOTING		24
APPENDIX II SERVICE AND SUPPORT		25
	WARRANTY TERMS.....	25
	PRODUCTION ENTERPRISE INFORMATION.....	25
	DATE OF PREPARATION OR REVISION OF THE USER MANUAL	25

Preface

Copyright and disclaimer

This document is a supporting user manual for the Sanity 2.0 System of Xiamen Zeesan Biotech Co., Ltd. Please keep the integrity of this document during use, and do not modify, process or extract without authorization.

The copyright of this document belongs to Xiamen Zeesan Biotech Co., Ltd., and all rights within the scope of law are reserved.

Xiamen Zeesan Biotech Co., Ltd. has made every effort to ensure that the content of this document is correct when it is delivered for printing, but the company still has the right to modify the content of this document without prior notice. The modified contents of the user manual shall prevail.

The structure design, operation software, supporting consumables and other intellectual property rights of this product belong to Xiamen Zeesan Biotech Co., Ltd., all buyers and users are requested to actively cooperate in the protection of relevant intellectual property rights in accordance with the requirements of the *Intellectual Property Law*. In case of any infringement, Xiamen Zeesan Biotech Co., Ltd. will investigate the relevant responsible person according to law and claim compensation for relevant losses.

The safety of the product has been fully considered in the design, and has passed the examination and approval of relevant standards and medical devices. Any failure to observe the safety precautions or other prompt information in this *User Manual* may result in damage to the instrument and the protection it provides. Xiamen Zeesan Biotech Co., Ltd. will not be liable for any personal injury or property loss in that case. The determination of relevant treatment shall be decided by relevant laws and institutions.

Intended use

Based on the principle of real-time PCR detection, the product is used together with supporting testing reagents for clinical qualitative detection of target nucleic acids (DNA / RNA) from human samples, including pathogens and human genes.

Product information

Product name

- Sanity 2.0 System

Product model

- Sanity 2.0

Contraindications

- This product is an in vitro diagnostic instrument without contraindications.

Product serial number and production date

- See the name plate of instrument for details.

Service life

- 5 years

The service life here is determined according to the theoretical calculation and aging test method. In the process of use, the user should keep, maintain and repair the product according to the requirements of the product manual. After the maintenance and repair, the product that is confirmed to be able to maintain the basic safety and effectiveness can be used normally.

Hardware configuration

Configuration name	Model or performance index
Processor	Intel (R) Atom (TM) CPU Z3735F @ 1.33GHz 1.83GHz
Storage	32 GB
Memory	2 GB
Peripheral device	Built-in touch LCD, printer, external bar code scanner

Software environment

Software name	Versions
Systems software	Windows 10
Application software	Sanity 2.0 System, version No. V2.1

Network conditions

None

Data and equipment (system) interface

By using a USB interface to connect the device for expansion, including mobile hard disk and U disk, it can realize the functions of program upgrade and data export.

User access control mechanism














Role based access control (RBAC)

Symbol description

The following symbols may appear in this *User Manual* or in the instrument.



Warning: Focus on the use requirements. Please read and operate carefully, or there may be personal injuries or instrument damages.

	Biological risk: There are potential biological pollution risks. Wear protective equipment when contacting or operating.
	UV radiation: There are potential UV radiation risks, please make sure the UV lamp is off or wear protective equipment before operation.
	Crushing of hands: There is moving or operating mechanical structure, beware of pinching hands during operation.
	Hot surface: There are hot parts or areas, and potential risks of scalding. Please take care when touching or operating.
	In vitro diagnostic medical device
	Electronic waste disposal
	CE marking
	Manufacturer's catalogue number
	Manufacturer's serial number
	Date of manufacture
	Authorized representative in the European Community/ European Union
	Medical device manufacturer
	Indicates the need for the user to consult the instructions for use.

Chapter I Safety Instructions



Please read this *User Manual* carefully before operating the instrument. For any questions, please contact the manufacturer.

1.1 Instrument safety

- The product should be used, transported and installed by professional personnel or under professional guidance, otherwise it may be damaged.
- After the installation of this product, it is necessary to remove the protective fixed structure before commissioning, otherwise the instrument will be damaged.
- There are vents on the side and back of the product. Please do not block or cover it to prevent damage caused by high temperature or fire.
- Without the authorization of the company or the manufacturer, the operator shall not disassemble the instrument, replace the part or debug the instrument. If necessary, these operations shall be completed by professionals after being approved and authorized by the company or the manufacturer.
- Do not move the instrument or open the cabin door forcibly during the operation of this product, otherwise it may cause personal injury or instrument damage.
- **In case of the following situations, please cut off the power supply immediately and contact the manufacturer:**
 - Abnormal sound, smoke, spark or peculiar smell during the operation of the instrument.
 - When the door of the instrument cabin is closed and the carrier is reset, it is stuck or abnormal.
 - Immersion, collision, fall or lightning strike of the instrument.
 - Electric leakage or liquid leakage of the instrument.



Please read carefully and use the instrument according to the above requirements, otherwise it may cause personal injury or damage to the instrument.



The operator shall be trained by the manufacturer or distributor before using and setting the instrument, otherwise it may cause personal injury or damage to the instrument.

1.2 Personal safety



This product is an active equipment. Operators are strictly prohibited to plug in and out power plugs and power switches with wet hands to avoid electric shock.



The power switch of this product is a ship-type mechanical switch, which is marked as (I) side to indicate that the power is on, and (O) side to indicate that the power is off.



During the operation of the product, it is strictly forbidden to put the head and hands into the cabin to prevent the operation structure from crushing and stabbing the head or hands.



The cabin door of this product is an automatic cabin door, which is driven by a high-power gear motor. During the opening or closing process of the cabin door, it is strictly forbidden to extend your head or hand into the cabin or the gap of the cabin door, otherwise it may cause pinch injury.



During and after the operation of this product, some modules may be hot. Please do not directly contact with the instrument immediately. Wait for enough time for cooling before operation after the instrument stops.



This product is equipped with UV lamp. High energy UV radiation may cause damage to eyes and skin. Please make sure that the UV lamp is turned off or wear protective equipment before operation.



The weight of this product exceeds the limit that can be carried by an adult alone. The process of moving and transportation needs the cooperation of many people or appropriate tools and methods, and one-man operation should be avoided.

1.3 Biological hazards

- The operation object of this product is nucleic acid, which has potential biological hazards whether it is from human or non-human sources. The operators of this product should fully understand the biological hazard pollution and have the ability of pollution prevention and control and cleaning, and take appropriate protective measures during operation or cleaning, including but not limited to wearing protective clothing, gloves, masks, goggles, etc.
- In case of liquid spilling or leakage during the operation of the product, stop the operation immediately and disinfect it with proper disinfectant to avoid the pollutant to form the air pollution that threaten the operator or laboratory environment.
- This product should be regarded as biohazardous waste after it is used, and should be treated according to the requirements of local applicable laws and regulations. Before storage, transportation and scrapping, the instrument shall have a bio-safety disposal (including cleaning and disinfection).
- The operators of this product shall abide by the local applicable laws and regulations, and deal with the consumables and wastes with biological hazards produced in the operation process.



Before, during and after using the instrument, the possibility of biological hazards should be fully considered, and the relevant laboratory specifications, the measures for the treatment of biological hazardous wastes and the relevant local laws and regulations should be strictly observed.

1.4 Electrical safety

- This product is connected to 100-240 VAC, which might cause serious personal injury. Live line maintenance is prohibited at any time. Be sure to cut off the power supply of the instrument and pull out the power plug before disassembling the shell.
- The shell of the product should be properly grounded through the power cord. The damage and open circuit of the internal or external grounding path of the instrument may cause electric shock.
- In order to avoid the fault of the grounding path of the product, the qualified standard three-phase power cord should be used and connected to the three-core grounding socket meeting the safety standards, with the voltage of 100 V-240 V (50 Hz/60 Hz), and can provide not less than 1000 VA power.
- The power socket, power plug and power cord should be kept away from heat source and

properly placed to prevent short circuit and accidental collision.

- In case of electric leakage (feel numb when touching the shell), please cut off the power supply immediately, pull out the power plug, and contact the manufacturer in time. Live working is strictly prohibited.
- The tubular fuse type of this product is F6.3A L250V P 5*20 mm, which is installed in the fuse box at the power socket on the back of the instrument, one of which is a spare Tubular Fuse.
- If the instrument is cut off unexpectedly, please check whether the power socket is cut off first, and whether the power plug, power cord and switch are properly configured.
- After troubleshooting the power connection fault, please disconnect the power supply, pull out the power plug, and then gently pry open the fuse box cover with a slotted screwdriver, take out the Tubular Fuse and check whether it has been fused.
- If the Tubular Fuse of the instrument is fused, please contact the manufacturer or distributor for professional replacement.



This product uses strong current network. Please use it in accordance with the above requirements and relevant specifications to prevent the risk of electric shock.



The blown Tubular Fuse shall be replaced by the manufacturer or an authorized professional. Improper installation or use of improper Tubular Fuse may cause the circuit system failure of the instrument or even fire.

1.5 Electromagnetic compatibility

- The EMC of this product is classified as group A and group I.
- This product is designed and tested according to Class A Equipment in CISRP 11:2015. In the home environment, this product may cause radio interference, which need to take protective measures.
- This product meets the emission and immunity requirements of EN 61326-1:2013 and EN 61326-2-6:2013.
- It is forbidden to use this product near strong radiation source (such as unshielded RF source), which may interfere with the normal operation of the instrument.
- It is recommended to assess the electromagnetic environment before using this product.



The manufacturer is responsible for providing the EMC information of the instrument to customers or users.



The user has the responsibility to ensure the electromagnetic compatibility environment of the instrument, so that the instrument can work normally.

1.6 Others

- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user.

Chapter II Operation Principle

2.1 System operation overview

In the process of sample detection, the system will perform in the following steps:

- Nucleic acid extraction with Magnetic Beads;
- Transfer the extracted and purified nucleic acid sample and sealant to the testing kit;
- Start the Real-time PCR detection.

2.2 System operation principle

The product is mainly composed of control unit, hot lid unit, thermal cycle unit, photoelectric unit, transmission unit (including nucleic acid extraction module and access board module), power supply unit, barcode scanner, embedded software (release version: V2.1), aiming to meet the requirements of real-time fluorescent PCR and melting curve analysis.

The principle of PCR is similar to the natural replication process of DNA. It consists of denaturation, annealing and extension with the specificity depending on the oligonucleotide primers complementary to the two ends of the target sequence. By repeating the three basic reaction steps, the target gene can be amplified millions of times after dozens of cycles. Therefore, the concentration of the target nucleic acid can be greatly increased and the detection sensitivity of the nucleic acid detection system is significantly improved.

The working principle of real-time PCR is to add fluorescent labeled probes into the PCR reaction system. In the process of PCR reaction, the amount of fluorescent signal excited is positively correlated with the number of target genes amplified. The qualitative or quantitative detection of target genes can be realized by real-time monitoring of the fluorescent value in the PCR reaction tube.

Compared with ordinary PCR detection methods, real-time PCR detection methods can not only detect the target genes quantitatively, but also have higher specificity and sensitivity.

The product adopts the fully-closed pre-assembled testing reagent mode, which can automatically split the sample, combine the target nucleic acid with magnetic beads, wash and elute the nucleic acid in the pre-assembled extraction reagent kit. After nucleic acid extraction, the extracted and purified nucleic acid solution is automatically added into the PCR detection tube with the cooperation of mechanical components and software control system. Then, under the control of software, the sample detection based on real-time fluorescent PCR analysis system is completed automatically. After the sample test, the software system automatically analyzes the test data and generates the test report.

Chapter III Instrument Description

3.1 Main components of the instrument

The product is made of control unit, hot lid unit, thermal cycle unit, photoelectric unit, transmission unit (including nucleic acid extraction module and access board module), power supply unit, barcode scanner, embedded software (release version: V2.1), etc.



Figure 1 Instrument host



Figure 2 Power cord



Figure 3 Barcode scanner

3.2 Main structure

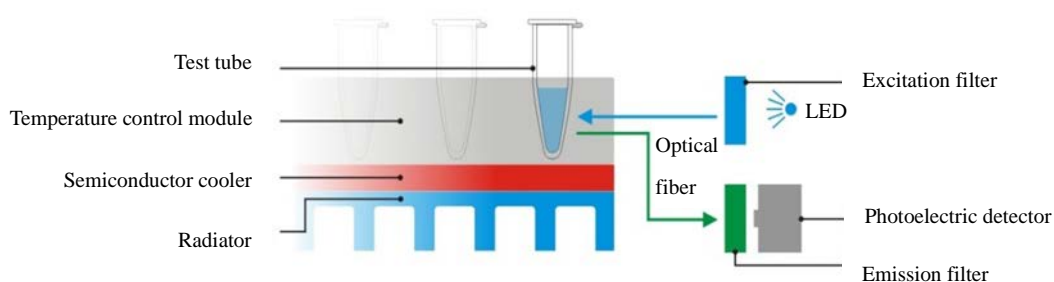


Figure 4 Structure diagram of nucleic acid detection module

3.3 Product overview



Figure 5 Schematic diagram of the front side of the instrument

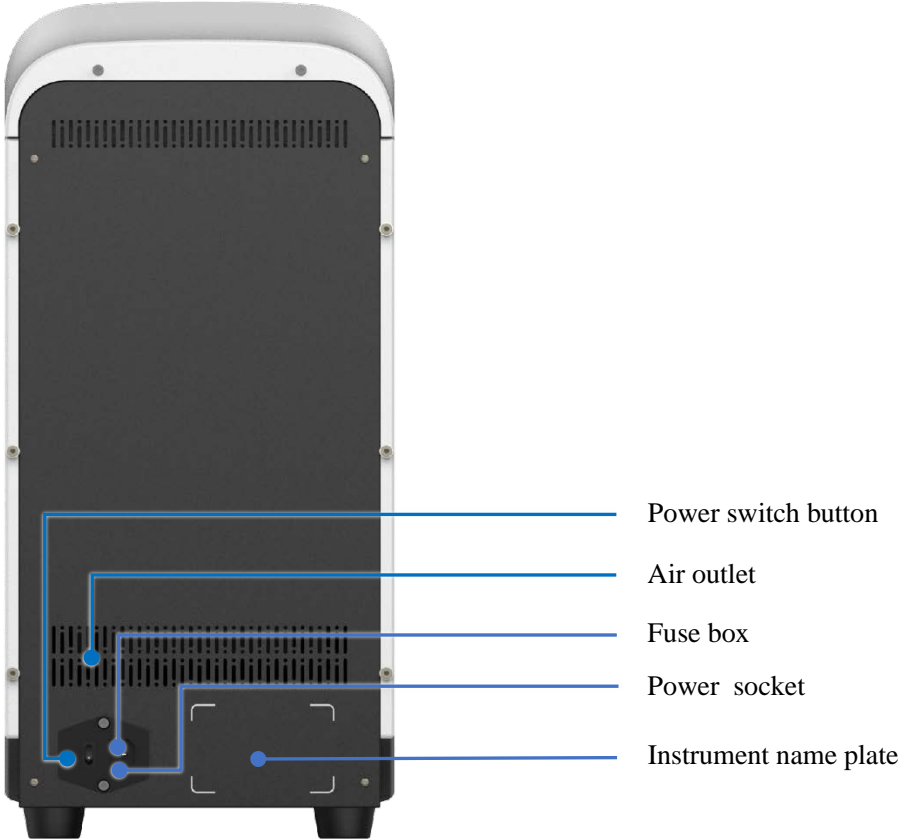


Figure 6 Schematic diagram of the back of the instrument

3.4 Instrument performance

Table 1 Instrument performance parameters

Performance parameters	Index
Sample flux	1~4 samples
Sample volume	1 μL ~2000 μL
Pipetting range	0 μL ~200 μL
Pipetting accuracy	$\leq 4\%$ (25 μL)
Technology of nucleic acid extraction	Magnetic-particle technology
Detection flux	24 wells
PCR reaction system	15 μL ~100 μL
Heating rate	$\geq 5.0^\circ\text{C/s}$
Cooling rate	$\geq 3.5^\circ\text{C/s}$
Temperature accuracy	$\leq 0.1^\circ\text{C}$
Temperature uniformity between holes	$\pm 0.1^\circ\text{C}$
Excitation wavelength of detection system	Channel 1: 470 nm; Channel 2: 530 nm; Channel 3: 580 nm; Channel 4: 630nm; Channel 5: optional; Channel 6: optional.
Detection wavelength of detection system	Channel 1: 510 nm; Channel 2: 565 nm; Channel 3: 620nm; Channel 4: 665 nm; Channel 5: optional; Channel 6: optional.
Applicable probe / dye	Channel 1: FAM / SYBR Green Channel 2: VIC / HEX / JOE / TET / TAMRA / Cy3 Channel 3: ROX / Texas Red Channel 4: CY5
Disinfection function	Time gated UV disinfection
Control method	Touch screen control that supports external computer control.
Communication interface	By using a USB interface to connect the devices for expansion, including mobile hard disk and U disk, it can realize the functions of program upgrade and data export.
Power Supply	AC 100 V-240 V, 50 Hz/60 Hz
Power	600 VA
Tubular Fuse	F6.3A L250V P 5*20mm
Size	260 mm×540 mm×570 mm
Weight	30 kg

3.5 Operation environment

- This product is only suitable for indoor use, where should maintain good ventilation and have no corrosive gas.
- This product should be placed on a stable and horizontal working table, avoiding direct sunlight or being close to heating equipment.
- The use space of this product should be at least 15 cm away from the surrounding objects or walls for the heat dissipation and ventilation of the instrument.
- The working environment temperature of the product should be between 15°C and 30°C, the relative humidity should be no less than 70%, and the atmospheric pressure should be between 85.0 kPa and 106.0 kPa.
- This product is not allowed to cover anything when it is running.



Be sure to provide a suitable operation environment according to the relevant requirements, otherwise it may cause damage to the instrument or shorten its service life.

Chapter IV Instrument Installation

4.1 Transportation and storage

- During transportation, it shall be protected from severe impact, rain and sun exposure to avoid damaging the instrument.
- The packaged product should be stored in an environment with ambient temperature of -40°C $\sim 55^{\circ}\text{C}$, relative humidity of no more than 93%, good ventilation and no corrosive gas.



After unpacking, please keep the original package for safe transportation in case of maintenance and inspection or changing the use site.



If the product is obviously damaged during transportation, please do not use it and contact the manufacturer or distributor in time!

4.2 Unpacking

4.2.1 Unpacking instructions

- After opening the package of the Sanity 2.0 System, please check whether the received parts are in accordance with the packing list. If you find any damage or missing items, please contact the company in time. Keep the packing materials properly for subsequent use or the company will not be responsible for any damage to the instrument due to poor packing on the way back to the factory.

4.2.2 Fixing block disassembly and installation

- Remove the two "Phillips" screws (Figure 7) on the back top of the instrument with a "Phillips" screwdriver.

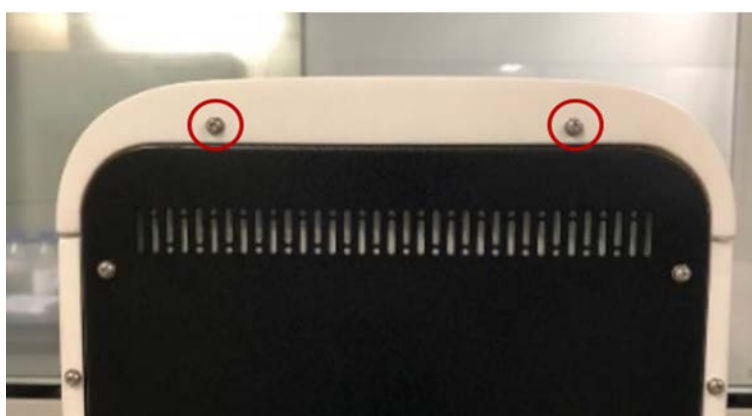


Figure 7 "Phillips" screws on the back top of the instrument



Figure 8 Top cover of the instrument

- Slide the top cover horizontally backward as shown in Figure 8, then remove the top cover and place it in a safe place.
- As shown in Figure 9, after unscrewing the fixing block screws with a M3 hexagonal wrench, fix the block on the top of the vertical plate, as shown in Figure 10.

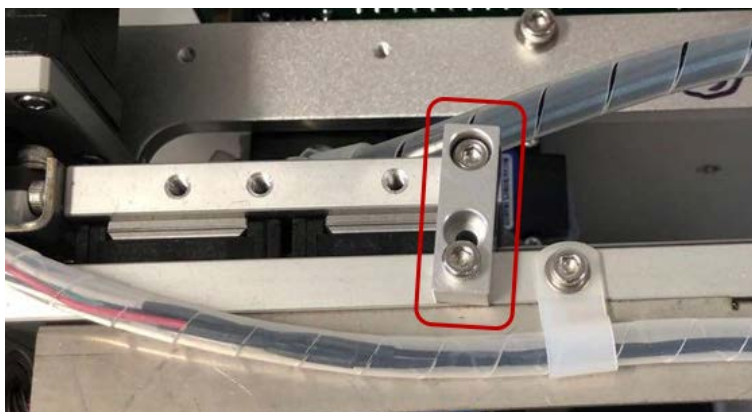


Figure 9 The fixing block



Figure 10 The fixing block fixed on the vertical plate

- After removing the fixing block, reinstall the top cover as shown in Figure 8, slide the top cover horizontally from the back until the assembly is complete and tighten the screws.
- Plug in the power, turn on the power switch (if the switch is on, press and hold the switch button until the touch screen lights up.), the touch screen will light up and the instrument will start internal self-testing, please wait and make sure the instrument shows "Connected". After the instrument completes the self-testing, the touch screen will show the [Main Interface] as shown in Figure 11.



Figure 11 The [Main Interface] of the touch screen

4.3 Packing list

Table 2 Packing list

Packing contents	Quantity
Sanity 2.0 System	×1
User Manual	×1
Power Wire	×1
Certificate of Analysis	×1
Certification	×1
Warranty Card	×1
Packing List	×1
Allen Key (2.5 mm)	×1
Phillips Screwdriver (5×75 mm)	×1
Barcode Scanner (with charge cable)	×1
Tubular Fuse (F6.3A L250V P 5 * 20 mm)	×2



If the product is obviously damaged during transportation, please do not use it and contact the manufacturer or distributor in time!

4.4 Inspection before the first run

- Turn on the power switch on the back of the instrument;
- Wait for a few seconds, the screen will light up automatically, indicating that the instrument is started successfully;
- The first start-up of the instrument does not require any operation after power on;
- After the instrument is started, the touch screen will enter the information initialization state. Do not operate the touch screen during the initialization process.



If the instrument fails to start or runs wrong, please contact the manufacturer or distributor in time!

Chapter V Operation Instructions

5.1 Typical operation process

Table 3 Typical operation process

Step	Task	Detailed description
1	Start the instrument	5.2.1
2	Create the test	5.2.2
3	Scan the kit and sample information	5.2.3, 5.2.4
4	Sample loading and kit placement	5.2.5, 5.2.6
5	Scan the operator information	5.2.7
6	Start the test	5.2.9
7	Complete the test	5.2.10
8	Report viewing and retrieval	5.2.11

5.2 Start testing

5.2.1 Start the instrument

Turn on the power switch on the back of the instrument (if the back switch is on, press the On/Off button for a long time until the touch screen lights up), the touch screen will be on, and the internal self-test of the instrument will start. Please wait for a while, and confirm that the instrument displays “connected”.



Power switch on (I), power switch off (O)!

After the self-test, the touch screen will display the [Main Interface] as shown in Figure 12.



Figure 12 Main Interface

5.2.2 Create the test

Click [New] in the [Main Interface], the instrument cabin door will be automatically opened and the kit carrier will be extended out, and the touch screen will display [New Test Interface], as shown in Figure 13.

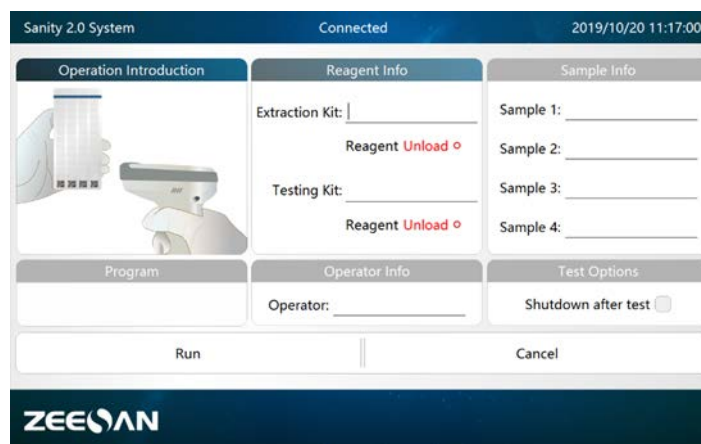


Figure 13 New Test Interface

5.2.3 Scan the kit information

Open the kit package and take out the extraction kit and testing kit.

Use the matching barcode scanner to scan the QR code or barcode on the extraction kit and the testing kit respectively (or manually input), and confirm that the “Program” displayed by the instrument are correct.

If the barcode of the kit is input incorrectly, the system will pop up the prompt box.

5.2.4 Scan the sample information

Use the matching barcode scanner to scan the sample barcode (or manually input). If there is no sample barcode, the sample information should be manually input for identification.

5.2.5 Add the sample

Tear off the sealing film of the extraction kit, and add the sample into the sample well of the extraction kit according to the scanning sequence.

***Note: Please refer to the kit instruction for specific operation.**

5.2.6 Place the kit

Place the testing kit on the testing kit carrier;

Place the extraction kit on the extraction kit carrier;

Confirm that the “Reagent Info” on the interface shows that the extraction reagent and testing reagent are all “Load”.

5.2.7 Scan the operator information

Use the matching barcode scanner to scan the operator information (or manually input).

5.2.8 Set automatic shutdown (optional)

According to the demand, you can select “Shutdown after test” to enable the automatic shutdown function, as shown in Figure 14.

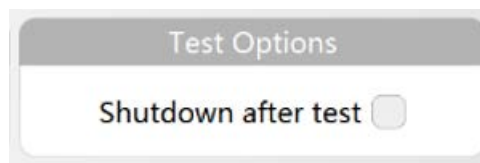


Figure 14 Set up automatic shutdown



If the automatic shutdown function is set up, the instrument will automatically shut down after completing the test. The automatic shutdown setting can be cancelled at any time in the process of test.

5.2.9 Start the test

Click [Run], the instrument will automatically start to run the test program and enter the [Test Interface], as shown in Figure 15. At this time, the indicator light of the instrument will turn green.

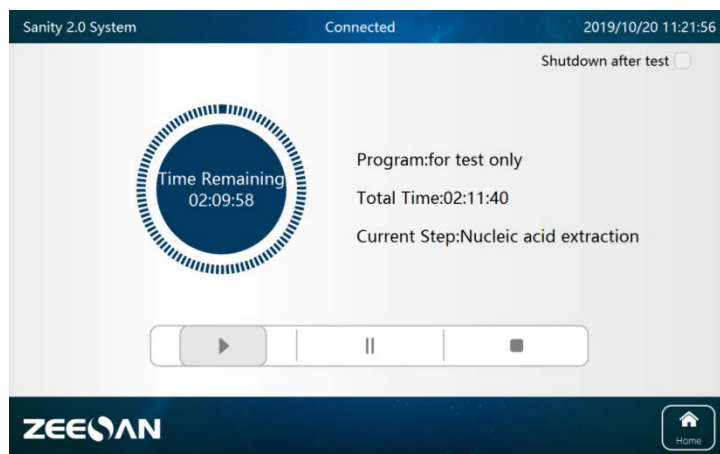


Figure 15 The Test Interface

After the test program is completed, the system will automatically enter the [Test Report Interface], as shown in Figure 16, and emit a prompt beep (if the automatic shutdown setting is selected, the shutdown countdown will pop up, if the operation is not cancelled, the instrument will automatically shut down).

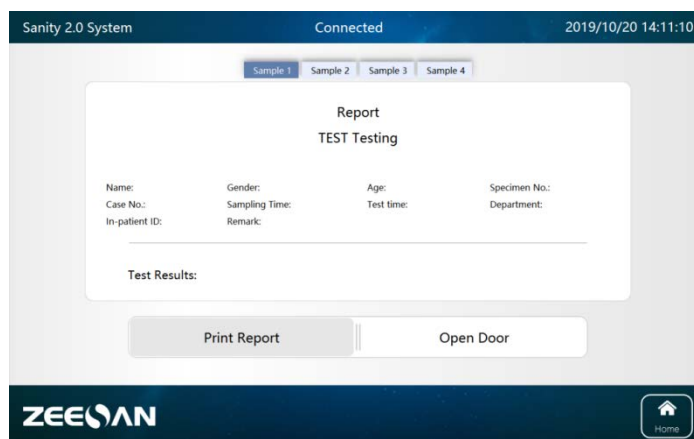


Figure 16 Test Report Interface

Click [Sample X] (X is the serial number of the target sample, from one to four) to switch and view the report. Click [Print Report] to obtain the paper report. Please tear down the report after printing.

5.2.10 Complete the test

After testing, please click [Open Door] and take out the extraction kit and testing kit according to the prompts. If you need to start the next test, please click [Continue] to enter the [New Test Interface] automatically. If there is no need for the next test, click the [Abort] button, the carrier will be automatically retracted and the cabin door will be automatically closed.



Complete the test process is the key step to ensure the normal operation of the instrument. Please follow the prompts to complete the necessary operations.



Figure 17 Complete the Test Interface

5.2.11 Report viewing and retrieval

Click [Report] in [Main Interface] to view the historical report information, as shown in Figure 18.

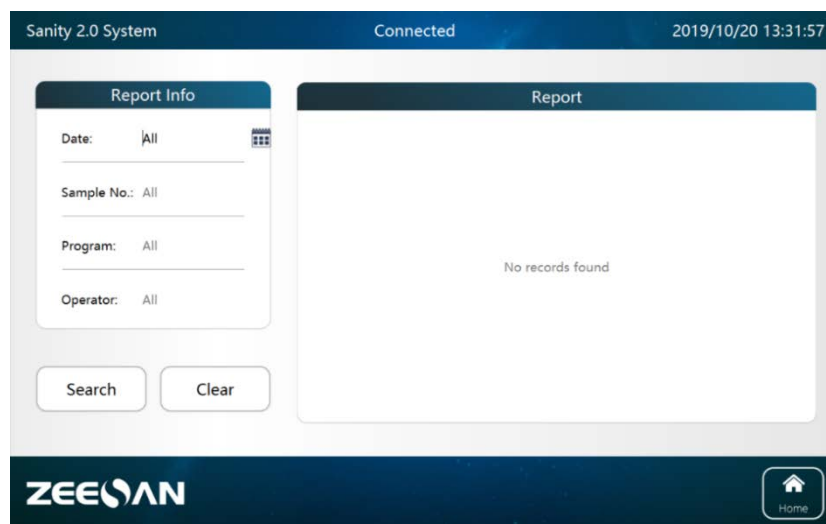


Figure 18 Historical Reports Interface

The test results can be retrieved according to the keywords such as “Date”, “Sample No.”, “Program” and “Operator”, and the retrieval results will be displayed in the column of “Report” (if the record matching the keyword cannot be found, it will prompt “No records found”).

5.3 UV lamp disinfection

Click the [UV] button in the [Main Interface] to enter the [UV Setting Interface], as shown in Figure 19.

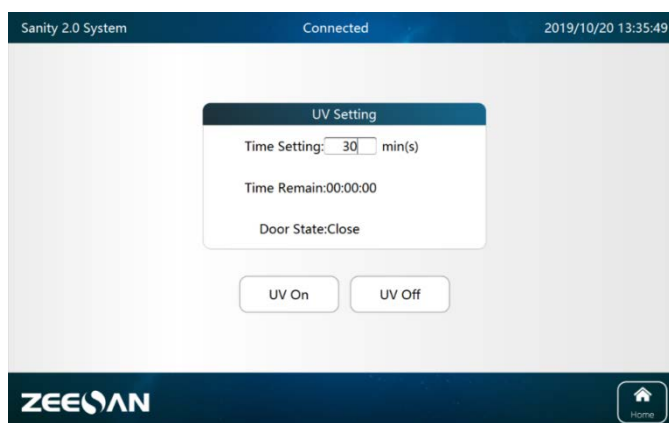


Figure 19 UV Setting Interface

In the [UV Setting Interface], you can set the disinfection time, check the remaining disinfection time and the opening or closing status of the door. The recommended disinfection time is 34 min. Click [UV On] or [UV Off] to turn on or off the UV lamp manually.



Considering the risk of UV radiation, once the cabin door is opened, the UV lamp will be automatically closed immediately. If the cabin door is open, the UV lamp cannot be turned on.

5.4 Instrument information

Click [Info] to enter the [Instrument Information Interface] to check “Model”, “SN”, “Software Version”, “Mainboard Version” and “Barcode Scanner”.

5.5 System shutdown

Click [Shutdown] in the [Main Interface], the touch screen will pop up the shutdown confirmation prompt (as shown in Figure 20), click [OK] button, the instrument will enter the shutdown process (as shown in Figure 20), and click [Cancel] button to return to the [Main Interface].

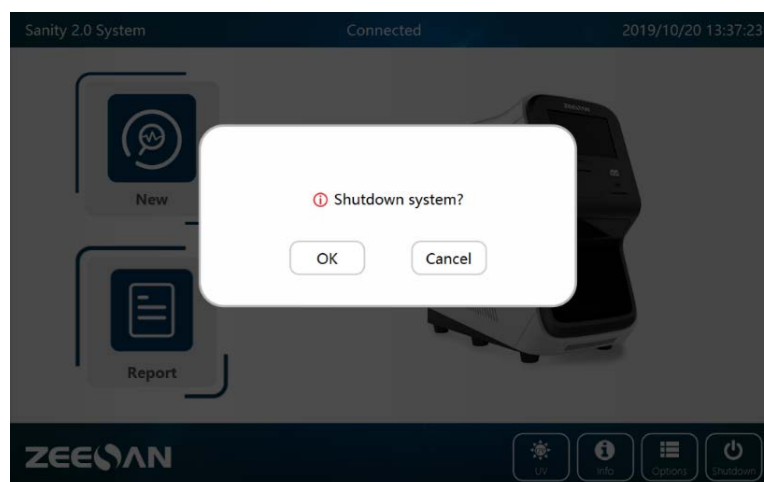


Figure 20 System Shutdown Notification

5.6 Development options

The functions of development options include “Edit Formula”, “Parameter”, “Record” and “Setting”, and user permissions need to be verified before viewing and modifying.



The development options include the parameter settings related to the normal operation of the instrument. The contents of the development options can only be set after obtaining the authorization and training of the manufacturer or distributor. Otherwise, the instrument may not operate normally or be damaged.

Click the [Options] button in the [Main Interface], and the system will prompt the information entry window of [Authentication], as shown in Figure 21. Through the drop-down list, you can select the corresponding account (admin, service, user) and input the verification password, then click the [Sign in] button. After passing the password verification, you will enter the management interface corresponding to the login account.

You can see the operation records in the user account management interface by clicking the [Record] button. Click [Setting] to enter the [User Setting Interface], you can set the “Password” and “Language”.

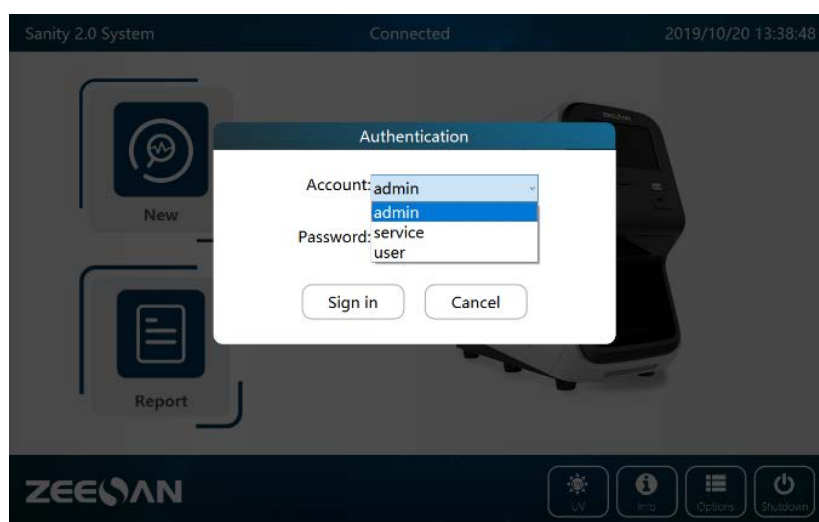


Figure 21 Authentication Interface

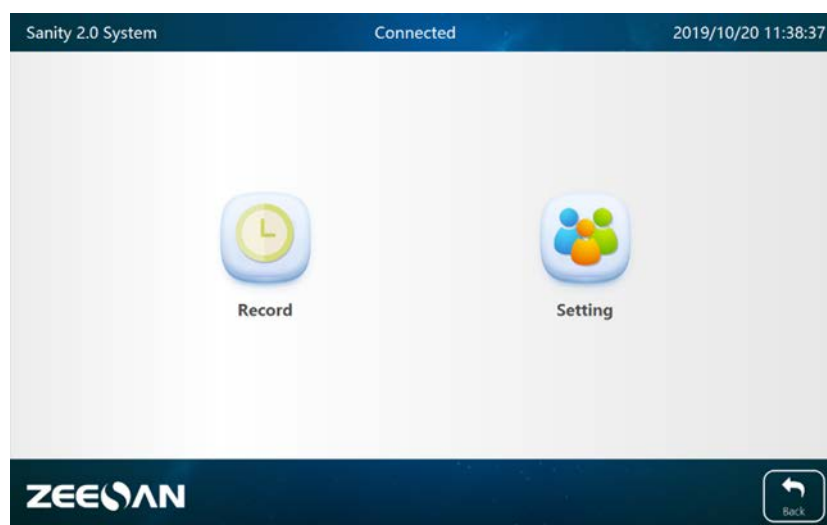


Figure 22 User Account Management Interface

Sanity 2.0 System		Connected		2019/10/20 14:08:46	
No.	Program	Running time	Status	Operator	



Figure 23 Running Records Interface

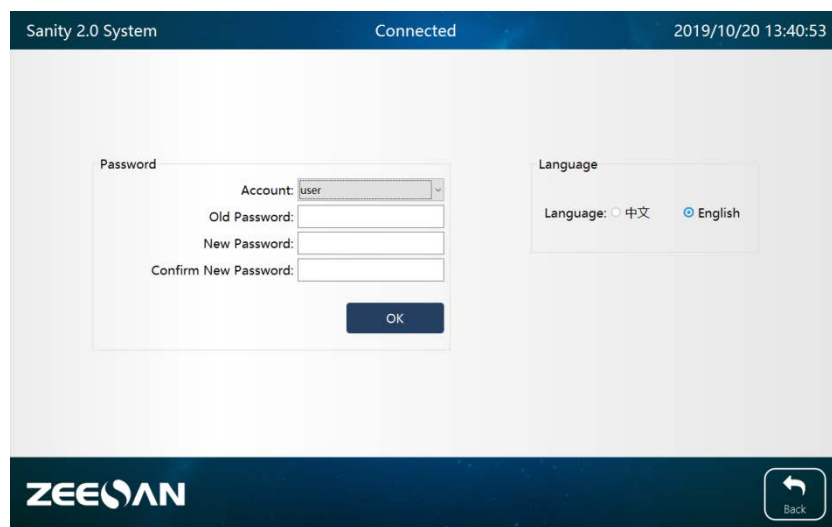


Figure 24 User Password Setting Interface



If the password verification fails, the system will prompt “Password error, please enter again”. If you forget the management password, please contact your distributor or instrument manufacturer.

Chapter VI Maintenance

6.1 Maintenance requirements

- This product has the function of preventing cross contamination and ensuring the accuracy of the results. In the case of normal use, it does not need a lot of maintenance. However, as a preventive measure, it is still necessary to check and clean the instrument regularly.
- Do not maintain the instrument when the power is not cut off or the instrument is running.
- Do not spray detergent or other liquid on the instrument, otherwise it may cause malfunction or damage.
- Do not use organic solvent, strong acid or alkali solution to clean the instrument, otherwise the instrument will be damaged.
- Do not deal with samples and reagents with potential biological hazards without taking appropriate protective measures.
- In case of any questions about the compatibility of disinfectants or cleaning agents with equipment parts or materials contained in the equipment, please consult the manufacturer or authorized professional maintenance personnel.



Please read carefully and clean and maintain the instrument according to the above requirements.



Wear appropriate protective equipment during cleaning and maintenance.

6.2 Waste disposal

- After each test, there will be sample solutions in the extraction kit and a large amount of amplification products in the testing kit, which have potential biological hazards and should be treated as soon as possible according to relevant regulations. Otherwise, it may contaminate the instrument and laboratory.
- In the process of waste disposal, the possibility of biological hazards should be fully considered, and appropriate protective equipment should be worn.
- Do not open the sealed tube cover after taking the testing kit out of the instrument to prevent aerosol pollution.
- This product and its accessories will contain lithium batteries, UV lamps, circuit boards and other electronic devices, which have potential electronic waste hazards, and should be disposed according to the relevant laws and regulations of the region or the state.



Wastes with potential biological hazards should be treated in accordance with relevant laboratory specifications and local laws and regulations.



Electronic waste disposal.

6.3 Instrument cleaning

6.3.1 Clean the shell of instrument

- Turn off the power of the instrument and pull out the plug.
- Use wet non-woven fabrics to wipe and clean the instrument shell. Use a neutral detergent to wet the soft cloth for wiping and cleaning if necessary.

6.3.2 Clean the touch screen

- Turn off the power of the instrument and pull out the plug.
- Clean the touch screen of the instrument with dry non-woven fabrics. Use a neutral detergent to wet the soft cloth for wiping and cleaning if necessary.

6.3.3 Clean the carrier

- Click [New] in the [Main Interface], wait until the cabin door is fully opened and the carrier is fully extended, turn off the power supply of the instrument and pull out the power plug.
- Use the wet non-woven to wipe and clean the instrument carrier. Use a neutral detergent to wet the soft cloth for wiping and cleaning if necessary.
- Plug in the power plug, turn on the instrument power, wait for the instrument self-test reset, the carrier will be automatically retracted, and the cabin door will be automatically closed.
- Click [Shutdown] in the [Main Interface], run the shutdown process, and then shut down the instrument.



It is strictly forbidden to clean the carrier without cutting off the power supply or when the instrument is still running, otherwise it may cause personal injury.

6.4 UV disinfection

- This product is equipped with UV disinfection device. You can click the [UV] button in the [Main Interface] to enter the [UV Setting Interface] to start the UV disinfection function and set the UV disinfection timing according to the actual needs.
- UV disinfection can be carried out before or after the test, and the UV disinfection function cannot be turned on during the test.



This product is equipped with UV lamp. High energy UV radiation may cause damage to eyes and skin. Please make sure that the UV lamp is turned off or wear protective equipment before operation.



Considering the risk of UV radiation, once the cabin door is opened, the UV lamp will be automatically closed immediately. If the cabin door is open, the UV lamp cannot be turned on.

6.5 Description of consumables

Table 4 List of consumables

Name	Model	Replacement period
Tubular Fuse	F6.3A L250V P 5*20mm	Replace after being fused



The blown Tubular Fuse shall be replaced by the manufacturer or an authorized professional. Improper installation or use of improper Tubular Fuse may cause the circuit system failure of the instrument or even fire.

Chapter VII Packing and Shipping

7.1 Packing steps

- The instrument must be installed with the fixing block before transportation, otherwise the instrument may be damaged during transportation, the specific packing steps are as follows:
- Remove the two "Phillips" screws (Figure 25) on the back top of the instrument.

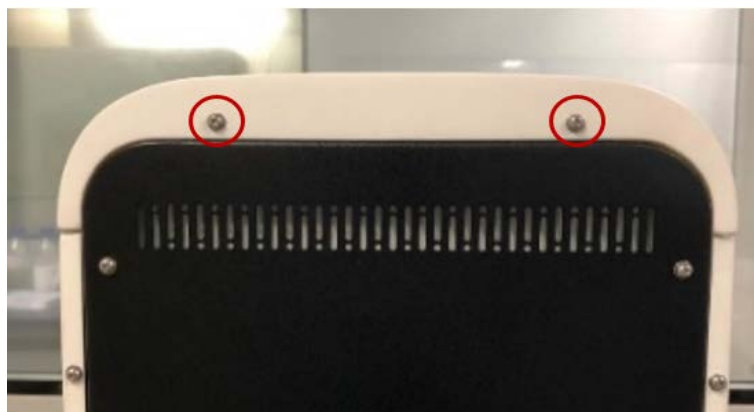


Figure 25 The "Phillips" screws on the back top of the instrument

- Slide the top cover horizontally backward as shown in Figure 26, then remove the top cover and place it in a safe place.



Figure 26 Top cover of the instrument

- As shown in Figure 27, after unscrewing the fixing block screws with a M3 hexagonal wrench, fix the block on the top of the 7vertical plate, as shown in Figure 28.

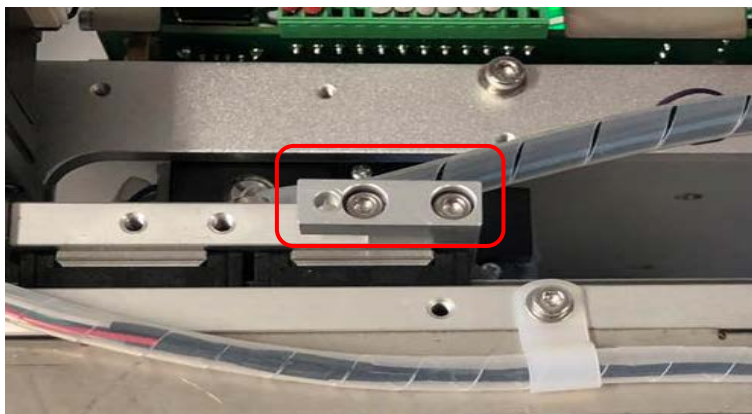


Figure 27 The fixing block

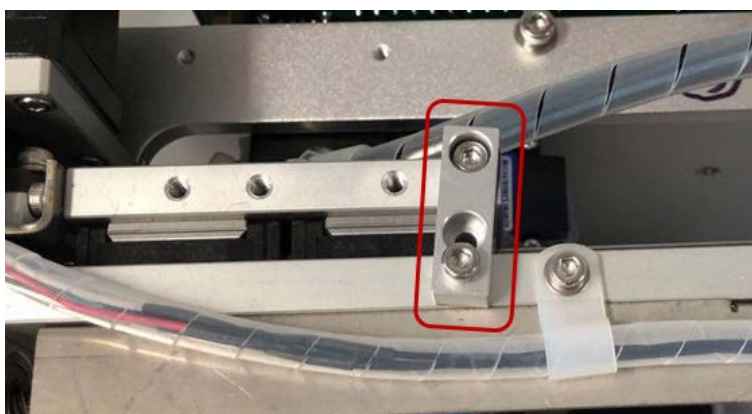


Figure 28 The fixing block fixed on the vertical plate

- After removing the fixing block, reinstall the top cover as shown in Figure 26, slide the top cover horizontally from the back until the assembly is complete and tighten the screws.
- Carefully pack the instrument into the carton.
- Cover the instrument with pearl cotton.
- Put all the accessories into the carton according to the packing list.
- Cover the carton with a flap and tape it tightly.
- Put the carton into a rigid transport box. For example: wooden or metal box.

Chapter VIII Calibration and Quality Control

8.1 Calibration

- The operator does not need to calibrate the product. This product has been calibrated and tested by the manufacturer before leaving the factory.
- However, it is suggested that the instrument be recalibrated 1 year after it is put into use or after it has been tested 1,000 times (the product will actively prompt this information).
- For recalibration, contact your distributor or manufacturer.

8.2 Quality Control

Quality control is an important part of in vitro diagnostic testing. Quality control will effectively ensure the normal operation of the instrument and the reliability of the test results.

This product can automatically control the internal quality of each sample. The system will adopt one or more of the following quality control methods during each test:

- Quality control of extraction process: ensure that all samples are extracted correctly. The quality control of sample processing is included in the kit, which is processed together with the sample and involved in nucleic acid detection for quality control.
- Endogenous quality control: standard quality control, included in the test reagent. Endogenous quality control is used to indicate the presence of inhibitors and ensure the effectiveness of the test.

Note: the specific quality control means and operation methods are subject to the instructions of the kit.

Appendix I Troubleshooting

No.	Faults	Analysis	Handling
1	No display on the touch screen.	The instrument is not powered on.	Power on the instrument.
		The power switch is off.	Turn on the power switch.
		The power supply is not connected correctly.	Plug in the power plug.
		Supply voltage mismatch or instability.	Choose the appropriate power supply.
		The Tubular Fuse has been overloaded and blown.	Replace the Tubular Fuse.
2	There is a fault prompt when the instrument is turned on.	Instrument self-check failure or communication failure.	Please turn off the power and turn it on again. If the problem still exists, please contact the distributor or manufacturer.
3	Instrument downtime or out of control.	Software failure or hardware failure.	Please turn off the power and turn it on again. If the problem still exists, please contact the distributor or manufacturer.
4	There was no result after test.	Sample error or test program error.	Test again after confirming the sample and test program.
		Failure of extraction kit or testing kit.	Test again after replacing with a new kit.
		Instrument failure.	Please restart and test again. If the problem still exists, please contact the distributor or manufacturer.
5	The UV lamp doesn't work.	The UV lamp is damaged.	Please contact the distributor or manufacturer.
6	The printer doesn't work.	Paper jam.	Open the cover to adjust the position of the print roll.
		Paper out.	Open the cover to check and add print paper
7	The barcode scanner cannot be turned on or auto power-off.	The scanner is low on battery or not connected to power.	Please charge or switch on the scanner.

Appendix II Service and Support

Warranty terms

- The warranty of the product is free of charge for one year from the date of acceptance.
- Any damage caused by human failure or unauthorized disassemble, it will not be covered by the free warranty.
- This *User Manual* must be read carefully prior to use. Any question, please call the following service phone or leave messages via e-mail.

Production enterprise information



Building 1#, 4F and A area 3F of Building 11#, No. 3701 North Xiang'an Road; 3F, 4F and 5F of No. 8045 West Xiang'an Road, (Xiang An) Industrial Area, Torch High-Tech Zone, Xiamen City, Fujian Province, 361101, P.R. China
Tel: +86-592-7615091
E-mail: info@zsandx.com



Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com

Date of preparation or revision of the User Manual

April 2, 2022

