Operating Manual

AUTOMOLEC 3000

Automated Nucleic Acid Purification and Real Time PCR System

V1.0

Autobio Labtec Instruments Co., Ltd.

AUTOMOLEC 3000

Automated Nucleic Acid Purification and Real Time PCR System

Operating Manual

2021/03

Trademark

DISCLAIMER

Autobio is not responsible for any damage or loss arising from incorrect operation, usage of wrong documents and failure to observing the manual, etc, no matter whether these damages are foreseeable or have already been existed, and no matter whether the loss or damage is direct, indirect, special (including the profit and data loss), consequential or incidental (arising from the use of the information irrespective of whether Autobio has advised as to the possibility of such damages), indicated in the contract, tort (including negligence), and not observing the warranty or liability, etc,.

In any case, the compensation amount paid by Autobio can not exceed the amount received from customer. The user will take full responsibility for the results obtained from operating the instrument as well as using the related documents.

Failure to observe the operating manual will result in harms to the user or the third party, and damages to the instrument or incorrect assay result. Autobio will not bear any responsibility arising from the aforementioned harms and damages.

This document can not be considered as substitute of official training of Autobio. The Automated Nucleic Acid Purification and Real Time PCR System shall only be operated by personnel who has been authorized and trained by Autobio.

CONTACT

In the event of any questions or doubts related to using the system, please send an email with a short description of the question to the address below or contact the post-sales service. Any suggestions for improvements to products and services are gladly acceptable.

	Autobio Labtec Instruments Co., LTD. No.199,15th Ave, National Eco & Tech Zone, Zhengzhou 450016, China
Tel	[86]-371-6798-5313
Website	www.autobio.com.cn

Email info@autobio-diagnostics.com

EC Representative

EC REP

OBELIS S.A.
Bd.Général Wahis, 53
1030 Brussels,
Belgium

In Vitro Diagnostic Medical Device

CE

IVD

This product is used for In Vitro Diagnostic purpose.

Waste Electrical and Electronic Equipment (WEEE)

In accordance with European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE), the presence of the left symbol on the product or on its packaging indicates that this item must not be disposed of in the way that normal unsorted municipal waste stream is mixed with other normal household-type waste. Instead, the responsibility should be taken by users to dispose of this element by returning it back to a collection area dedicated for recycling the waste of electrical and electronic equipment. The waste, which may be harmful to physical and potentially mental health or makes it impossible to keep a favorable environment, must be collected separately, observing the relevant legal regulations effective, which makes for recycling and minimizing the bad effect on human physical health and the environment. In order to acquire more information with respect to the correct disposal of this product, please contact your local authority or the dealer who supplied this product.

Operating Manual

Table of Contents

The manual is mainly used for giving instructions to users for instrument related operation and general maintenance, which includes the following: general description, safety features, description and quality control of function and operation, measures taken in case of emergency, product labelling and maintenance, *etc.*

1 General Description

1.1 Safety Information

1.1.1 Safety Features

Safety labels are affixed on the instrument to remind the user of safety. Please read the label and the operating manual carefully prior to operating the instrument. If any questions, please contact Autobio.

Prior to usage, user must be trained by Autobio to avoid risks caused by incorrect action.

1.1.2 Protective Device

In the middle position on the left side of the instrument, there is an STOP switch. If the instrument breaks down or other accidents occur during the running, you can press this switch to abort the operation of the instrument.

The instrument is equipped with UV lamp. Before the UV lamp is turned on, please make sure that the lid of the instrument is completely closed. After the UV lamp is turned on, do not look into directly the UV lamp and keep a certain distance from the instrument. If the lid or door of the instrument (including the abandoned cabin) is opened when the UV lamp is turned on, the instrument will disenable the UV lamp and the user needs to restart the UV lamp.

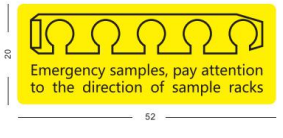
The instrument has an interlock device, which is used to protect users from the risk caused by the movement of moving parts during the operation of the instrument. Do not open the lid or door during normal operation, otherwise the stop function will be triggered and the experiment will fail.

The product can only be used by personnel who has been trained to qualified.

1.1.3 Safety Symbols

This manual employs the following symbols and signal words to indicate hazards or instructions. The safety instructions are always placed before an action.

Symbol	Description

	Caution! Please read important information located on the symbolic label or in this manual, or it may indicate that there is a specific risk when usind it with other symbols..
	Caution! Possibility of Electric Shock! The components shall not be inspected or repaired by a technical engineer not from or not authorized by Autobio
	Biological hazards. Human serum or blood products with potential risk of infection may be present in certain areas of the instrument and related liquid treatment equipment. Materials in these areas should be disposed of in accordance with proper laboratory procedures or in accordance with local laws and regulations.
	Warning; Crushing of Hands! Pay attention to the movement of the instrument cover when you open or close it.
	Ultraviolet lamp warning! UV lamps are used in certain areas of the instrument. Warning: do not look the UV lamps directly.
	Cut off Power supply! When you are repairing the instrument, please cut off the power supply of the whole instrument, otherwise there may be electric shock danger.
	Warning; Crushing of Hands! When you put the sample rack again, make sure that the sample rack has been reset.
	Sample rack direction label: Pay attention to the orientation of the rack when you place it from the emergency unit.

	It is a label present on the container of purified water.
	It is a label present on the container of waste liquid. Be careful of biological risks!
	It is a label present on the container of solid waste bin. Be careful of biological risks!.
	Alternating Current.
	Protective Conductor Terminal.
	“OFF”(Power).
	“ON”(Power).
STOP	Stop Button. During the operation of the instrument, press the STOP button, and the instrument will stop.

	Electrostatic Discharge (ESD). Certain areas of the instrument may be damaged by electrostatic discharge.
	Warning: High temperature surface.
	Disposal of Electrical and Electronic Equipment: The equipment must not be processed according to the conventional waste disposal. It is the responsibility of the user to return it to the waste collection point of the electrical and electronic equipment for recycling.
	In Vitro Diagnostic Medical Device.
	Consult Instructions for Use.
	Note that the sample rack should be fully putted into the SRK.

CAUTION:

Failure to observe the content of symbols or operating manual, including the warnings, precautions and prompts, and using the damaged or missing safety symbols, will cause system damage or adverse impacts on system functionality; or may result in physical injury or deterioration in the state of health, damage to property or material!

1.1.4 General Safety·

The operating manual gives important instructions for handling the system. Safety instructions must be observed at all times. Before or during the process of operation, the following items must be observed:

CAUTION:

1) Do not perform any operations which are not described in the manual. If trouble occurs, please call post-sales service.

2) The operating manual must be accessible to the user at any time.

3) As for maintenance and service, it is forbidden to modify the device and replace the components or accessories of the instrument.

4) It is not allowed to use parts which are not provided by Autobio. It is not permitted to remove protective device.

5) Personnel without authorization of Autobio can not install or maintain the device, nor make any changes during installation.

NOTE:

Improper connection between the device and the peripheral devices with mains supply, as well as usage of damaged cables may result in severe personal injury even lethal consequences and property damage (e.g.fire).

1.1.4.1 Liability

It is the users' responsibility to comply with national and local law's regulations and laboratory procedures for installation and operation of the instrument.The manufacturer has done everything possible to guarantee that the equipment functions safely, both electrically and mechanically.

Autobio is not liable for any loss or damage including consequential or special damages resulting from the misuse of the contained information or other fault of personnel and contractors. Additionally, the manufacturer assumes no liability for any damages, including those to the third parties, which is caused by improper use or handling of the system.

The instrument may only be used in accordance with its intended use. Only use the consumables and accessories described in the manual.

1.1.4.2 Technical Condition

AutoMolec 3000 corresponds in its design and construction to the current state of the art technology. Unauthorized modifications or changes, especially such that affect the safety of the staff and the environment, are generally not allowed.

CAUTION:

1) Any manipulation of the safety device is prohibited! In case of an accident manipulations of the safety equipment will be interpreted as deliberate!

2) The operator must only operate the device in a sound and operationally safe condition. The technical condition must always comply with the legal requirements and regulation.

3) Prior to every usage, the device must be checked for damage and sound condition.

4) Any changes in the device affecting its safety must be reported to Autobio by the the operator.

1.1.4.3 Requirements for the Operating Personnel

AutoMolec 3000 must only be used by professional laboratory personnel taking into consideration the operating manual of AutoMolec 3000 and the corresponding IVD kit manual.

Apart from the information in the AutoMolec 3000 operating manual and manual of the corresponding IVD kits, the regulatory requirements of the applicable country of use must be observed and complied with. The operator must ascertain the latest version of these regulations.

CAUTION:

1) The device must only be commissioned, operated and serviced by trained personnel instructed in technical safety.

2) The operation or servicing of the device by minors or individuals under the influence of alcohol, drugs or medication is not permitted.

3) It must be ensured that only authorized personnel works at the device. The operator must be familiar with the dangers arising from samples and excipients. Suitable personnel protection equipment must be worn.

4) Any changes in the device affecting its safety must be reported to Autobio by the the operator. Prior to pauses or at the end of the work, appropriate skin cleaning and protection measures must be carried out.

5) Eating, drinking and smoking at the location of the device are prohibited!

1.1.5 Biological Risks

When operating the device or handling related liquid, such as reagent, human serum, blood products, etc., user may be exposed to potentially infectious materials. Please strictly comply with Good Laboratory Practice when dealing with biological hazards or repairing and maintaining the Device:

Please take appropriate protective measures, such as wearing disposable gloves, waterproof lab coats and safety goggles.

Observe national and local laboratory standards and regulations.

Materials used in the assays must be considered potentially infectious agents. They should therefore be decontaminated and disposed of in accordance with standard and regulations

of laboratory specified by local government.

The following articles should be disposed as potential biohazard:

a) All in-vitro diagnostic instruments, pre-treated kit, patient sample, calibrators based on serum, QC materials and medical wastes.

b) Articles coming into contact with the potential biohazard, such as pipettor tip, sample tube or cup, reaction vessel, waste container, washing tank, etc,.

c) When hoses and parts containing liquid become aged or damaged, please stop using them immediately and contact with after sale service or local distributor to change them.

NOTE:

Please contact Autobio if the instrument needs to be scraped, and it can not be disposed as a regular article.

1.1.6 Electrical Hazards

The device does not pose uncommon electrical hazards to operators if it is installed and operated without alteration and is connected to a power source that meets required specifications. It is essential to the safe operation of any system to have basic electrical hazard awareness. So only personnel strictly observing the related national rules and local regulations for the safe electrical operation of the system should perform electrical servicing. Life threatening electrical voltages may occur in the interior of the AutoMolec 3000, and please strictly observe the elements of electrical safety, which include but are not limited to the following:

CAUTION:

1) Any work on the interior of the device may only be carried out by the service engineer of Autobio and specially authorized technicians.

2) Keep liquids away from all connectors of electrical or communication components.

3) Do not touch any switches with wet hands.

4) Do not replace the removable mains cable of the device by a mains cable that dose not meet the specifications (without protective ground conductor).

5) Any defects, such as loose connections, faulty or damaged cable, must be repaired without delay.

6) Do not put connecting cables at accessible place in order to avoid squeeze or damage.

7) Do not interrupt any electrical connection or service any electrical or internal components while the power is on.

NOTE:

Use an independent supply source to prevent device malfunction at site. It is strictly prohibited to add any other device to the socket of AutoMolec 3000 (if available) without permission of Autobio.

Severe personal injury or extensive damage to the device may occur. It will not trigger severe personal injury with lethal consequences and property damages unless not observing the rules and regulations for the safe electrical operation.

1.1.7 Physical Hazards

For most automated (or semi-automated) device, there is potential physical injury or bodily harm from moving mechanical components whenever the system is running because of following hazards: radiation (laser light, etc,.), heavy objects, trip hazards, moving parts of the instrument and sharp units, etc,.

Commissioning or installing the instrument must comply with the operating manual. Basic safety elements include but are not limited to the following (If applicable):

1) Do not touch directly with the sharp metal edges.

2) Do not overlook or ignore a safety equipment.

3) Keep all protective covers and barriers at right place.

4) Body part is not allowed to enter into the mechanical movement arrange.

5) Do not contact with the probes that are contaminated with potentially infectious material.

6) Do not look into the laser beam.

7) Wear off watches and reflective jewelry before operating the laser module.

NOTE:

Do not wear clothing or ornaments that could have an interference with the system.

1.1.8 Fluids Hazards

Users may be exposed to hazardous chemicals or agents when handling kits and calibrator or disposing the liquid waste. Observing the instructions below can minimize the risks of fluids hazard.

1) Cleaning or decontamination shall not cause a direct hazard, such as an electrical hazard or a hazard arising from corrosion or weakening of structural parts.

2) Absorb the spill with absorbent material.

3) Observe the manual of IVD reagent kits.

4) Wear appropriate protective equipment, such as impervious gloves, protective goggles and clothing to protect eyes and skins from contacting with hazardous fluids.

1.1.9 Electromagnetic Wave Interference

AutoMolec 3000 fulfills the corresponding requirements for transient emissions and interference resistance from IEC 61326 series. Only cables provided by Autobio can be used to minimize electromagnetic wave interference. Please read the following content carefully and ensure the ambient environment is appropriate:

1) AutoMolec 3000 is designed and tested according to CISPR Class A. Under some circumstances, it may cause radio interference, please take protective measures.

2) It is recommended that the electromagnetic environment should be evaluated before operation.

3) Do not operate the instrument near sources of strong electromagnetic radiation (such as unshielded, deliberately operated high frequency sources), as this may affect proper operation of the device.

NOTE:

1) Autobio is responsible for providing electromagnetic compatibility information of AutoMolec 3000.

2) User is responsible for maintaining the electromagnetic compatibility environment where AutoMolec 3000 can work properly as intended use.

1.1.10 Other Residual Hazards

Notwithstanding the manufacturer has try as possible as they can to reduce the risks to an acceptable level, such as inherent safe design and protective measures, users may be still at an unfavourable situation.

In regards of risk management, the system has been designed and manufactured based upon the standard EN ISO 14971.

The materials and components of the AutoMolec 3000 and the reagents used on the device do not endanger the safety or health of users. Autobio has applied many principles for reducing risks, include but not limited to the followings :

1) Eliminate or reduce risks as far as possible (an inherently safe design and construction);

2) Take the necessary protective measures related to the risks that cannot be eliminated, which can refer to the 1.1.5-1.1.9;

3) Inform users of the residual risks due to any defects of the protective measures adopted, indicate any particular training required, and provide operator with information of protective device/safety equipment;

4) Estimate the risks of hazardous situations, taking into account the severity of potential harm and the possibility of its occurrence by the application of an appropriate FMEA (Failure Mode Effect Analysis) methodology;

NOTE:

Autobio assumes no responsibilities concerning the losses or damages arising from the improper operations or maintenance by unauthorized personnel. It is recommended that users contact service engineer immediately in case emergency occurs.

1.1.11 Ergonomic

Based on the ergonomic principles, the AutoMolec 3000 is designed regarding to the user habits, interface layout, information prompts and software interface operation safety etc,. to reduce discomforts fatigue, physical and psychological stress. If the user needs other functions, please contact customer service of Autobio.

The documents and materials related to safety operation are included in the accessory case, e.g. the operating manual, waste liquid container, reaction vessels, and fuse etc,.

1.2 Reporting Instrument Anomalies

Users are encouraged by Autobio to report any anomalies observed in the performance, appearance, labelling or packaging of instrument. Autobio or its local representatives will carry out a thorough analysis of possible defects, and encourages users to report the anomalies in sufficient detail, e.g. serial number, UDI, product model or catalogue/reference number, along with a description of the relevant observations and supported with photographic or other descriptive material if available. It is advisable that products with suspected defects be quarantined and processed according to the advice of Autobio authorized representatives or local agent. Please preserve the whole product, together with the packaging material for further analysis.

1.3 Vigilance Information

If the unlikely case of a suspected hazardous situation caused or affected by the use the instrument of Autobio occurred, please contact Autobio or its local representatives directly and without delay, which can refer to the important contact information of chapter 1.4. Additionally, local competent authorities have standard reporting forms available for reporting possible adverse effects of IVD medical devices, and users should follow any local regulations or guidance provided by the local authorities.

1.4 Product and Manufacturer Information

Product Information:

Product Name: Automated Nucleic Acid Purification and Real Time PCR System

Product Model: AutoMolec 3000

Manufacturing Date: Refer to the nameplate label of the instrument.

Lifetime: 7 Years
Applicable Software Version: V1

NOTE:

The lifetime of the instrument is closely related to the operating environment and frequency of use. Regular maintenance can duly extend the lifetime. If there is any problem, please call customer service or access the website of https://www.autobio.com.cn/.

If the components mounted on the AutoMolec 3000 were to be changed, the only way to purchase would be from Autobio other than other manufacturers. Do not open the cover of the AutoMolec 3000 during running, otherwise it will abort the assay.

Manufacturer:
Name: Autobio Labtec Instruments Co., Ltd.
Legal Address: No.199, 15th Ave, National Eco & Tech Zone, Zhengzhou 450016, China
Tel: [86]-371-6798-5313

Post-sales Customer Service:
Name: Autobio Diagnostics Co., Ltd.
Legal Address: No.199, 15th Ave, National Eco & Tech Zone, Zhengzhou 450016, China
Tel: [86]-371-6798-5313

NOTE:

Please prepare the serial number of the instrument before contacting post-sales service.

2 Product Description

2.1 General Description

Product Name: Automated Nucleic Acid Purification and Real Time PCR System
Product Model: AutoMolec 3000

AutoMolec 3000 is an in vitro molecular detection instrument for sample extraction and amplification analysis.

Clinical diagnosis can be made only after the physician evaluate all results of clinical and laboratory tests. Single project test can not be taken as a diagnosis proof.

NOTE:

Clinical diagnosis can not be made just on the basis of single item test of this product. Clinical diagnosis can be made only after the physician evaluates all clinical check and lab tests.

2.2 Structure Composition

AutoMolec 3000 is composed of the instrument, computer (optional), external barcode reader, control machine software (release version V1) and client software (release version V1). The instrument is composed of purification unit, PCR module, waste unit, electric cabinet and ultraviolet unit. The purification unit is composed of ESK, CKU, SRK,SPP, RAU, RPP, TI, WU, RLU and PSU.

2.3 Intended Purpose

AutoMolec 3000 is an in vitro molecular examination instrument integrating sample extraction and amplification analysis. It is based on the principle of polymerase chain reaction (PCR) and real-time fluorescence monitoring technology, automatically completes a series of operating steps from nucleic acid extraction and purification to amplification and examination. AutoMolec 3000 is intended for quantitative and qualitative examination of analytes in serum, plasma, whole blood, swab and sputum nucleic acid samples (DNA/RNA) from human body, such as pathogens and human gene polymorphism items, etc.

Authorization: The product can only be used by trained professional inspectors or laboratory technicians, *etc,*.

Contraindications: None.

Sample can be tested: serum, plasma, blood, swab and sputum.

Project can be tested: pathogen, human Gene Polymorphism

2.4 Working Principle

AutoMolec 3000 can extract the nucleic acid based on the principle of the split samples releasing nucleic acid after adding the specific chemical reagents, and the nucleic acid is separated and purified by magnetic bead adsorption method, i.e. after the separation of nucleic acid adsorbed on the magnetic bead surface under certain conditions, with specific buffer from the surface of magnetic bead dilution down in order to realize the separation and purification of nucleic acids and enrichment, and the purification of nucleic acids and consists of a mix of PCR amplification reagents reaction system, through the index of temperature cycle to achieve specific fragment amplification, and through the specific fluorescent dye or the specificity of the fluorescent tag probe to detect the amplification process, thus the qualitative or quantitative analysis is realized

2.5 Performance Parameter

Product Name	Automated Nucleic Acid Purification and Real Time PCR System
Sample Number	60 samples (circular rotor), priority lane for emergency samples.
Projects analyzed simultaneously	No less than 20 items at one time
Kit slot	20, online order and replacement.
Sample Carrier	12 sample racks can be placed at one time (5 samples/racks)
Capacity	Maximum 30 tests/h
Consumables Supply	Continuous supply
Test Mode	It supports independent temperature control, independent testing, on-call test, and sample purification and amplification are integrated.
Reagent temperature	2℃ ~ 8℃
Temperature scope of incubation unit	Low temperature: 37℃± 2℃; High temperature: 80℃± 3℃.
Temperature indicator of thermal cycle unit	Heating rate: Average rate：50℃~90℃, no less than 3.0℃/s; Maximum rate: 50℃~90℃, no less than 6.0℃/s; Cooling rate: Average rate：50℃~90℃, no less than 2.5℃/s; Maximum rate: 50℃~90℃, no less than 4.0℃/s; Temperature control accuracy: Temperature control accuracy≦0.2℃; (4) Temperature accuracy:

	a. The absolute value of the difference between the measured value and the set temperature (60℃) is not greater than 0.1℃; b. The absolute value of the difference between the measured value and the set temperature (90℃) is not greater than 0.3℃. (5) Temperature uniformity: a. The temperature uniformity is no larger than 0.2℃ at 60℃; b. The temperature uniformity is no larger than 0.5℃ at 90℃. (6) Temperature duration accuracy: The relative deviation between the temperature duration and the set temperature duration is within ±5%.
Fluorescence intensity test repeatability	The coefficient of variation (CV, %) of each calibrated dye with high, medium and low concentrations was not more than 1.5% in the range of product determination.
Fluorescence intensity test accuracy	Within the product measurement range, 10 test holes were randomly selected and each calibration dye with high, medium and low concentrations was used for detection. The coefficient of variation (CV, %) of fluorescence value at the same concentration was not more than 5%
Fluorescence interference of different channels	The fluorescence detection intensity of other channels was not higher than the fluorescence threshold of the target channel
Sample test repeatability	When the nucleic acid specimen is at high, medium and low concentration , the coefficient of variation of CT value of corresponding channel is not more than 3%.
Liner	(1) Sample liner: Linear evaluation of samples (5 gradients) was conducted, and the absolute value of linear regression coefficient R was not less than 0.980. (2) Fluorescent linear: A series of diluted fluorescent dye samples (5 gradients) were tested, and the linear regression coefficient R was not less than 0.990
Dispensing probe accuracy and repeatability	(1) Sample probe: 100ul accuracy: 100ul±5ul, CV≤2%; The accuracy was 600ul±12ul at 600ul, and the repeatability was CV≤2%; (2) Reagent probe: 10ul accuracy: 10ul±0.5ul,CV≤4%; 50ul accuracy 50ul±2.5ul, CV≤3%; (3) BF probe: 100ul accuracy: 100ul±3ul,CV≤2%; 2000ul accuracy 2000ul±40ul, CV≤2%;
UV-radiation intensity requirements	No less than 400mW/㎡.
Safety requirements	Comply with the requirements of IEC 61010-1, IEC 61010-2-010, IEC 61010-2-081, IEC 61010-2-101.

EMC requirements	Comply with the requirements of BS EN 61326-1 and BS EN 61326-2-6.

2.6 Operation Environment

AutoMolec 3000 can only be operated in door, and it must not be operated with flammable, explosive or volatile substance. The operating personnel must be familiar with the location of the fire-fighting equipment in the operating room of the device. It is intended used in medical institution and laboratory of hospital and so on. It can be operated when the operation environment condition in the table below is sound:

Item	Requirements
Temperature	15 ~ 30 ℃
Relative Humidity (RH), (non-condensing)	≤85 %
Altitude	≤2000 m
Atmospheric Pressure	85 kPa~106 kPa
Power Supply	100-240V, 50 Hz/60 Hz
Rated Power	2.4 kVA
Pollution Degree	Level 2
Sound Pressure Level (in decibels)	< 70dBA
EMI	Stay away from sources with strong electromagnetic interference , good grounding environment
Interference from other Instruments or Equipment	High power, strong amplitude, strong light illumination instrument and equipment will have a certain impact on the function and performance of the instrument, so stay away from such equipment.
Interference from Other Instruments or Equipment	Keep away from high-power, high-amplitude, high-intensity illumination instruments and equipment

Water Quality Requirements	Purified water should meet relevant requirements

2.7 System Specifications and Features

2.7.1 Weight

Item	Weight
Instrument (before adding supply materials and samples)	670 kg
Computer	25 kg or refer to the documentation of computer's manufacturer

2.7.2 Power Requirement

Component	Rated power
Instrument	Power Consumption:2.4 kVA Voltage Fluctuation : Not more than ± 10% of the nominal voltage. Overvoltage Category : II
Computer	Refer to documents of manufacturer

2.7.3 Electromagnetic Compatibility Information Description

1. Automated Nucleic Acid Purification and Real Time PCR System meets the emission and disturbance immunity requirements of IEC 61326-1.
2. The equipment is designed and tested according to CISPR Class A. In the home environment, the device may cause radio interference, and protective measures should be taken.
3. It is recommended to evaluate the electromagnetic environment before the application of AutoMolec 3000.
4. Do not use the instrument next to an intense radiation source (such as an unshielded RF source), otherwise it may interfere with the normal operation of the instrument.
5. AutoMolec 3000 meets the requirements of IEC 61326-1 and IEC 61326-2-6. The limits of radiation emission and terminal harassment voltage meet the requirements of Class A of GROUP 1 in IEC CISPR 1. Please use in non-residential areas.If used in residential areas, please take the following protective measures (if in doubt, please contact our technical service personnel or local dealers):

1) Mobile devices should be far away from AutoMolec 3000.
2) Use a slot-grounded three-hole socket.
3) Ensure that other equipment and the AutoMolec 3000 can not be used together with the same power connector.
4) Use a slot-shielded cable.
5) According to the requirement of this manual of AutoMolec 3000 to reposition the it.
6) Connection to external devices must meet the requirements of IEC 61326-1 and IEC 61326-2-6.

NOTE:

1. Autobio is responsible for providing customers or users with the electromagnetic compatibility information of the AutoMolec 3000.
2. It is the user's responsibility to ensure the EMC environment of the instrument so that the AutoMolec 3000 can work normally.

2.7.4 Space Requirements

The following table lists the dimensions of the instrument and external equipment. Please check the table in advance before installation.

Instrument with Cover Plate and Drawer Closed	2400 mm×900 mm×1900 mm (L×W×H)
Instrument with Cover Plate and Drawer Open	2400 mm×1450 mm×2150 mm (L×W×H)
Clearance Required to Ventilation, Safety Operation and Maintenance	Front ≥ 800 mm, Rear≥ 600 mm, Top≥ 300 mm

2.7.5 Electronic Requirements

2.7.5.1 Power Supply

The power supply should meet the requirements of the following table in order to avoid damage to the instrument.

Item	Requirements
Circuit Power Supply	220 - 240 V ~,50-60 Hz, single-phase power supply
Circuit Specific	Dicated cable
Power Cable Plug	250 V ~ , 16 A
Circuit Outlet	It is not more than 3 m away from the instrument and compatible with the 16 A plug of the instrument.
Voltage Fluctuation	It shall not exceed 10 % per cycle.

Maximum Resistance between Instrument Ground Wire and Safety Grounding of Lab	Not more than 0.1 Ohm
Overvoltage Category	II

Item	Requirements
Circuit Power Supply	100 - 240 V ~,50 -60 Hz, single-phase power supply
Circuit Specific	Dicated cable
Power Cable	300/500V 3*6.0mm²
Circuit Outlet	It is not more than 3 m away from the instrument and compatible with the 30 A power cord of the instrument.
Voltage Fluctuation	It shall not exceed 10 % per cycle.
Maximum Resistance between Instrument Ground Wire and Safety Grounding of Lab	Not more than 0.1 Ohm
Overvoltage Category	II

The UPS power supply shall meet the following requirements:

Minimum Output Capacity	3 kVA
Output Voltage	220 V ~
Output Frequency	50/60 Hz
Output Waveform	Sine wave
No Load Running Time	At 3 kVA, ensure that the instrument can run for at least 110 minutes when power is cut off.
Certification	CE

2.7.5.2 UPS for the Instrument

If you need to use an uninterrupted power supply (UPS) as a backup power supply, It is recommended that UPS with a local grounding isolation and low battery power indicator be used. You can contact the technical support department of Autobio for the recommended backup power supply.

NOTE :

If power is to be cut off from all parts of the instrument, disconnect the equipment and the power supply providing the energy.

2.7.5.3 Computer Configuration

The configuration requirements in the following table are minimum requirements, and the actual configuration shall not be lower than the minimum configuration.

Item	Requirements
CPU	i3 or above with a primary frequency of 2.5 GHz or above
RAM	8 G or more
Hard Disk	500 G or more
Operating System	Windows 10
Communication Port	At least 3 RJ45 network ports and 2 RS232 serial ports
Driver	Build-in
Monitor Resolution	1280×1024 or above
USB	At least 3 USB interface

NOTE:

1) Improper connection of instruments and peripherals to power supply or damage of connection cables may cause serious personal injury and may cause fatal consequences and material damage (e.g. fire).

2) Improper positioning (installation or operation) or improper environment of the instrument, which cannot be shut off or separated from the main power supply during operation, may cause fire or serious damage to the instrument.

2.8 Used in Combination with Other Products

The instrument needs to be used in combination with the corresponding IVD kits designated by Autobio. End-user must read the manual of IVD kit carefully before usage to avoid unreliable assay result (such as expiration date, etc,.).

CAUTION:

1) Autobio shall not bear any liability due to non observance of IVD kit manual or using IVD kit not designated by Autobio.

2) It is strictly prohibited to add any other instrument to the socket of the instrument

except the instrument installed by the authorized representative of Autobio.

3) The instrument fulfills the safety requirements of IEC61010 series, and if it is anticipated to be used with a device certified in accordance with IEC60950, please contact engineers authorized by Autobio for consultation to avert damages to the equipment.

3 Installation & Precautions

The installation and commissioning of AutoMolec 3000 must be executed by service engineers or personnel authorized by Autobio. Do not take out the instrument from the package without the engineer presenting at the site. After installation, any other device can not be plugged in the socket connected with the instrument.

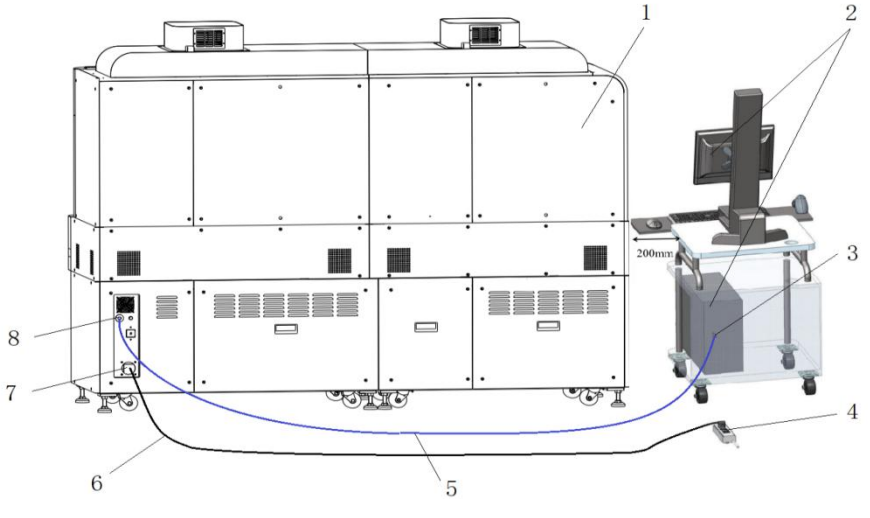
3.1 General

The instrument can not be installed and used in a laboratory with potentially explosive atmosphere. It can only be operated under the working conditions (temperature, altitude, no direct sunlight exposure and humidity) specified in this manual. End-user is obliged to assess whether the above requirement has been met.

3.2 Connection with Computer System

The instrument shall be connected with the computer by a communication wire, which shall be connected according to the label on the instrument and the computer.

No.	Items	No.	Items
1	Instrument	5	Ethernet cable
2	Computer	6	Power cord
3	Computer communication port	7	Power input port
4	Power socket	8	Instrument communication port



3.3 Installation Precautions

Precautions should be taken before installation, which include but are not limited to the followings:

1) The instrument shall be installed on a flat and hard ground with a bearing capacity of no less than 350 kg/㎡.

2) The instrument must be installed in a position convenient to operate the power switch and stop the instrument running.
3) If the instrument needs to be transported or moved, please contact a professional engineer.
4) The side housing must be installed completely before the instrument is powered on.
5) The power cord should be connected to a power supply with ground protection.
6) If the equipment is not used in the way specified by the manufacturer, the protection provided by the instrument may be damaged.
7) The instrument needs to be adjusted before use by professionals, and make sure that the instrument is in a horizontal position before normal operation.
8) Please close all lids and doors of the instrument during normal operation.
9) Autobio will not be liable for injuries or losses caused by the use and connection of the instrument by untrained or unauthorized persons.
10) It is strictly prohibited to change and/or modify the conditions and functions of instrument covers. If you want to remove the lid and door of the instrument, please contact the manufacturer. The service personnel or the engineer of the manufacturer will remove them with the specified screwdriver and hexagon wrench.
11) When the lid of the instrument is open, it is strictly forbidden to touch moving parts of the instrument or getting closed to them with hands, arms, shoulders or face/ head.
12) If the instrument has been moved, it must be reinstalled by authorized service personnel, otherwise system abnormalities may occur.
13) Replaced instruments, packaging materials and all components must be disposed in accordance with applicable local and national laws, regulations and laboratory procedures.
14) The distance between the air outlet on the top of the instrument and the roof should be at least 50cm, and it should be far away from the room entrance, fans, ventilation ducts and other areas with frequent air flow.
15) Please use the power cord provided by the manufacturer. If you need to replace the power cord, please contact the service personnel

3.4 Warranty

Autobio shall guarantee the instrument according to the terms of the contract agreement for your purchase of the equipment or reagents.

The customer should be responsible for the implementation of the preventive maintenance

procedures and cleaning procedures. In the event of instrument failure due to customer's failure to perform the relevant maintenance procedures within a specified time interval, Autobio shall not be responsible for free maintenance, and the maintenance cost and component cost incurred by the maintenance shall be borne by the customer, including:

1. Warranty labels on the instrument cover are missing or damaged.
2. The serial number of the instrument is not the serial number sold by our company or has been altered.
3. The instrument and accessories are not installed, powered and operated in accordance with this manual and accessories instructions.
4. Damage in transit.
5. Damage caused by reagent dropping or contacting with corrosive substances or gases.
6. The instrument is disassembled and replaced by the customer or any unauthorized technician.
7. The instrument was damaged by an unknown voltage.
8. Damage caused by natural disasters or force majeure.
9. Software or hardware failure or damage caused by improper operation or computer virus.

If the product fails during the warranty period, Autobio will provide free repair or replace the corresponding parts at Autobio's discretion. The warranty period of replaced spare parts is limited to the warranty period of the instrument.

The warranty service is non-transferable and does not apply to products damaged by misuse, alteration, improper transportation or repaired by personnel other than the manufacturer or authorized service provider.

CAUTION:

This product is designed in accordance with the relevant standards, and certified in accordance with IEC 61010-1 safety standards.

It is safe to use the instrument in accordance with the product manual. Do not attempt to modify this product in any way, otherwise it may result in:

- The manufacturer no longer makes any quality guarantee.
- Not meeting IEC 61010-1 safety requirements.
- Some potential safety hazards.

Autobio shall not be liable for any damage to the instrument if the product is used for any purpose other than the intended purpose or if it is repaired by engineers other than Autobio staff or authorized agents.

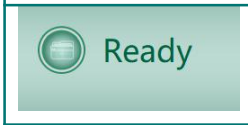
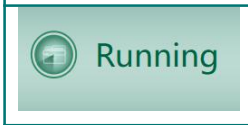
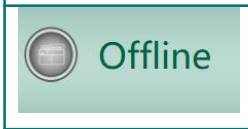
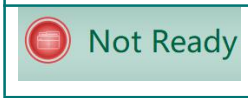
4 Operation Description

4.1 Function Introduction

4.1 System Status and Control

4.1.1.1 Status Prompt

AutoMolec 3000 displays six statuses. The current status is displayed in the upper left corner of each screen.

System status	Description
	Ready: The module is ready for normal operation.
	Running: The system is being tested.
	Pause: No new tests are planned, but currently planned tests will continue.
	Offline: The control machine is disconnected from the client communication.
	Amplification: Abnormalities occur during the module test, extraction has been completed, and amplification continues.
	Not ready: The module is not ready and must be reinitialized before anything else can be done.

4.1.1.2 System Shortcut Button

There are six system shortcut command buttons, under normal operating conditions, the button is green, select a button, you can view the relevant interface. The color of the button will change under the following conditions: 1) the amount of remaining available supply material needs to be noted, 2) sample treatment has problems, 3) event log reports warnings or exceptions. The button will flash yellow or red until you select a button to view the alarm data or have completed the alarm processing.

Shortcut	Description	Button Color and Description

Button		
	Display the "exception detection" queue on the sample management interface to view the sample detection request information where an exception occurs. If the number of exception detection queues is empty, the button displays the normal color.	Red One or more detection requests have an exception during detection.
	Display the "Work Pending" queue view of the sample management interface to view the sample detection request information in the work waiting. If the number of work pending queues is empty, the button displays the normal color.	Yellow A work pending occurs when a detection request cannot be made for some reason.
	It displays the supply reagent management interface for information about the required supply reagent and calibration.	Yellow The system needs to supply materials or perform calibration in order to complete the requested inspection.
	It displays a high volume of consumables management interface for reagents, lotions, and consumables available, as well as available space in solid waste containers and waste liquid containers. If the consumable remaining available is in a normal state, the button displays the normal color.	Yellow The substrate may be about to expire, or a waste liquid container may be full. Red The substrate is empty or expired, or the waste liquid container is full.
	Display the quality control setting management interface to set the quality control, or check the quality control results. If the latest quality control test results are normal, the button	Red Quality control results are not within acceptable expected values.

	will display the normal color.	
	It displays the event log management interface for information about events generated by the system. In this interface, troubleshooting information for warning or warning events can be displayed. If the log alert event is viewed, the button displays the normal color.	Yellow The system generates a general warning event indicating that something needs your immediate attention. Red The system generates a serious warning event indicating a serious failure or error condition.

4.1.1.3 System Control Button

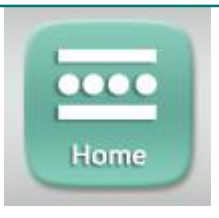
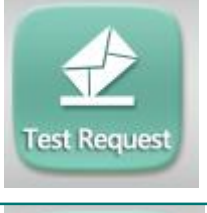
The functions of the three system command buttons are stop, pause, and start operations.

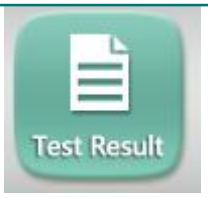
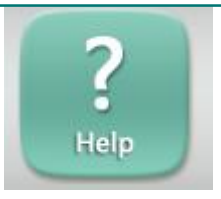
Control Button	Description
	It is used to select to stop detection operation when the system is running or paused. After clicking the button, the system stops processing and cancels the ongoing detection. System status: Run Not ready  Note When you choose to stop the detection operation, all detection requests in operation will be stopped, including those that have entered the sampling line. Please confirm your choice. The system needs to be reinitialized before the test can be performed again.
	It is used to choose to pause detection operations while the system is running. After clicking the button and completing the planned tests, no new tests are planned, but samples that have already been processed continue to be

	processed. System status: Not ready Amplification
	When the system is ready and paused, the detection operation can be started or resumed by clicking the button. System status: Run  Note Precautions for starting detection in a ready state: If consumables, solid waste, waste liquid, temperature in the incubator and freezer do not reach the normal range, testing cannot be started.

The functions of the three system command buttons are module A start, module B start and stop operation respectively.

4.1.1.4 Other Buttons and Status Description

Other Buttons	Description
	Select the button to return directly to the main interface
	Select this button to go directly to the test request interface
	Select this button to directly enter the real-time monitoring interface

	Select this button to directly enter the test results interface
	Select the button to provide system help instructions
	Display time
	Display temperature status Normal / General warning / Serious warning

4.1.1.5 Indicator Light Status Description of the Whole Instrument

1. Indicator light of the whole instrument:

Color	Status
Not bright	Power off
Red	Not ready
Green	Ready
Green light flashing	Running, no exception
Yellow light flashing	Running, no exception

2. Indicator light in the centralized display area of consumables:

Color	Status
Not bright	Not loaded
Green	Normal
Yellow	Warning of remaining quantity

3. Indicator light in consumable area and refrigerated reagent area:

Color	Status
Not bright	Not loaded or not ready to load

Green	Loaded, not used
Green light flashing	In using

4.1.2 Running Mode

Operating modes of AutoMolec 3000 can be divided into two types:

System Model	Description
	Online mode: The system is in online mode, without editing and testing in AutoMolec 3000, the samples are directly placed in the sample loading area, and the instrument can obtain sample information and test request data from LIS system through communication with LIS system (laboratory information system) according to the sample number read (barcode). Method: [System Settings] - [LIS Communication Settings] - [To Receive LIS Request] - [LIS interface], and select [Open].
	Stand-alone mode: The system is in stand-alone mode, inputting sample data and test request information manually through the operation interface. Method: [System Settings] - [LIS Communication Settings] - [To Receive LIS Request] - [LIS interface], and select [Close].

NOTE

In online mode, the system can read manually entered sample data and detection request information, or obtain it from LIS system.

PROMPT

In stand-alone mode, samples whose barcode number failed to be read in online mode can be entered manually, and then sample data and detection request information can be obtained from LIS system through “Obtain LIS Request” function (in system settings, LIS communication switch must be set as “on”).

4.1.3 Shut down and Restart

4.1.3.1 Shut down the Instrument

CAUTION:

As shown in the figure, press the power switch on the back right side to shut down the instrument..

At this point, the interface state of the computer system becomes “Offline”, and the instrument power display lamp is off, indicating that the instrument has been turned off.

System status: Ready Not ready

Go to the back of the instrument, turn the switch behind the instrument to position O, and turn off the power (Position O).

At this point, the computer system interface changes to “Not ready”, indicating that the instrument has been turned off.

When the power is off, please wait for at least 15 seconds before turning it on, otherwise a system failure may occur.

WARNING

Shutting down and restarting the computer or instrument must follow these steps, otherwise it may damage the instrument or destroy the system database.

4.1.3.2 Shut Down the Computer

There are two ways to shut down a computer:

1. Use user interface (UI) software

Start the main program, enter the maintenance interface, and then click shut down the system, the computer will shut down.

2. Use a computer keyboard

Press Ctrl + Alt + Delete and select Shutdown.

NOTE:

1. Use user interface software to perform standard shutdown.
2. When the instrument is not in use for a long time, select “Instrument sleep” on the maintenance interface to make the instrument enter the power-saving mode.

System status: Ready Not readt

Use the keyboard to turn off the computer.

If the user interface is not available, follow this step to turn off the computer using the keyboard.

PROMPT

When the user interface fails to shut down the computer, you can use the keyboard to close the user interface.

1. Press Ctrl + Alt + Delete on the computer keyboard at the same time.
2. Select the “Shutdown (U)” menu.
3. Select one of the close options, depending on whether you want to restart the computer immediately.
4. Select OK.
5. If the keyboard is not responding, shut down the computer by turning off the power. Hold the power switch down and hold for at least 10 seconds. Wait at least 20 seconds before restarting your computer.

4.1.3.3 Shutdown Instrument for Long Term

Shut down the entire AutoMolec3000 system if you intend to move the instrument or shut down the system for an extended period of time (more than 5 days). Before shutting down the system, please contact technical support to confirm your decision.

WARNING

In these steps, you will come into contact with potentially infectious material. Handle and dispose of these biologically hazardous materials in accordance with proper laboratory procedures. The hand, eyes and face must be properly protected.

NOTE

Turning off the instrument will turn off the refrigeration in the reagent storage area.

System status: Ready Not ready

1. Operating day maintenance procedure.
2. Remove all racks and sample containers from the sample basket device.
3. Remove and refrigerate all kits.
4. Clean large capacity waste liquid containers.
5. Clean up solid waste containers.
6. Turn off the computer and the instrument, including the power switch of the instrument and the computer.

4.1.3.4 Hibernate

In the sleep mode, the instrument enters the power-saving mode and only supplies power to the refrigeration system to keep the refrigeration system working normally, while other

components stop working.

System status: Ready Not ready

1. Select "Maintenance" in the main menu interface.
2. Select "Hibernate" on the maintenance interface.
3. Select "Yes" in the confirmation window.

4.1.3.5 Restart Instrument

When the instrument power is off, use this step to restart the AutoMolec 3000 instrument. Move the switch behind the instrument to position I.

PROMPT

If the computer is turned on, the system state of the system software interface is "offline".

1. Confirm that the main top cover is closed.
2. Turn on the power switch at the back of the instrument and confirm that the STOP button is in the spin state.
3. If the computer is not running, restart the computer and start AutoMolec 3000.
4. If the user interface software is running, please perform "Reinitialize" in the maintenance interface.
5. If the instrument is not successfully initialized, please contact technical support.
6. Wait for the system to restore the internal temperature. If the instrument is turned off for a short time, the system will restore the internal temperature in 15 to 20 minutes. Do not load samples on the instrument and open the main top cover until all temperatures are in the desired range.
7. Please confirm that the system is "ready". If the system cannot be "ready" after about 60 minutes, please contact technical support.
8. If it is the first operation after the daily maintenance, please clean it the next day and continue the normal operation.

4.1.3.6 Restart the System after a Long Time Shutdown

After a long shutdown, use this step to restart AutoMolec 3000 systems.

Switch on the instrument and the computer.

Restart the instrument.

Restart the computer and the automatic sampling management control system.

WARNING

In these processes, you will come into contact with potentially infectious materials. Handle and dispose these biologically hazardous materials in accordance with proper laboratory procedures. The hand, eyes and face must be properly protected.

1. Restart the instrument.
2. Restart your computer and AutoMolec 3000 systems.

NOTE

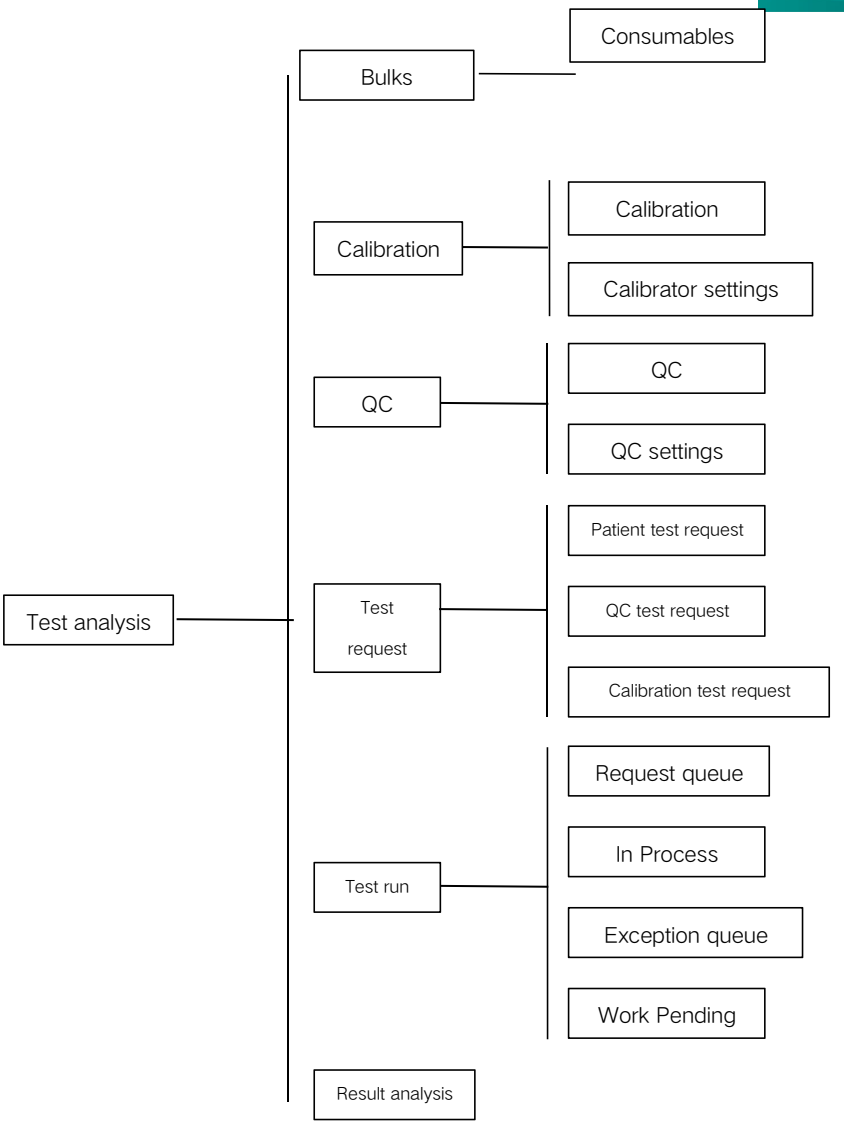
1. Wait for the system to restore the internal temperature. Since the system has been shut down for a long time, it may take some time for the internal temperature to recover. Do not load or open the instrument's main cover until temperature of all areas is within the desired range.
2. Confirm that there is sufficient supply of cleaning buffer. If necessary, replace the cleaning buffer container.
3. Confirm that the waste liquid container is not full. Empty the liquid waste tank and solid waste container if necessary.
4. Check the supply of reaction containers and add more if necessary.
5. Load new substrate bottle.
6. Load the required kit.
7. Perform daily cleaning routines.
8. Clean up solid waste.

CAUTION

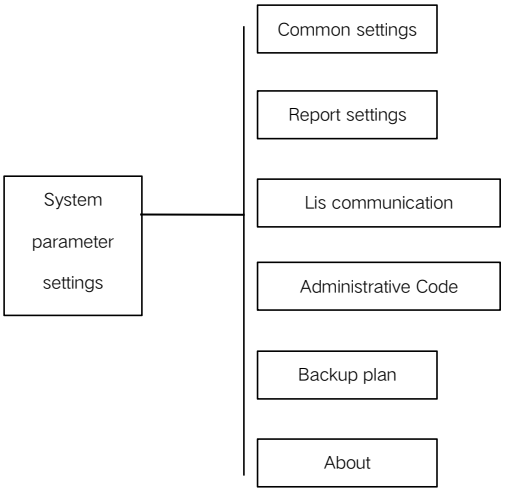
Please contact your local engineer when you turn off the instrument for a long time, such as more than three weeks, to restart and run the instrument again.

4.1.4 Navigation Function

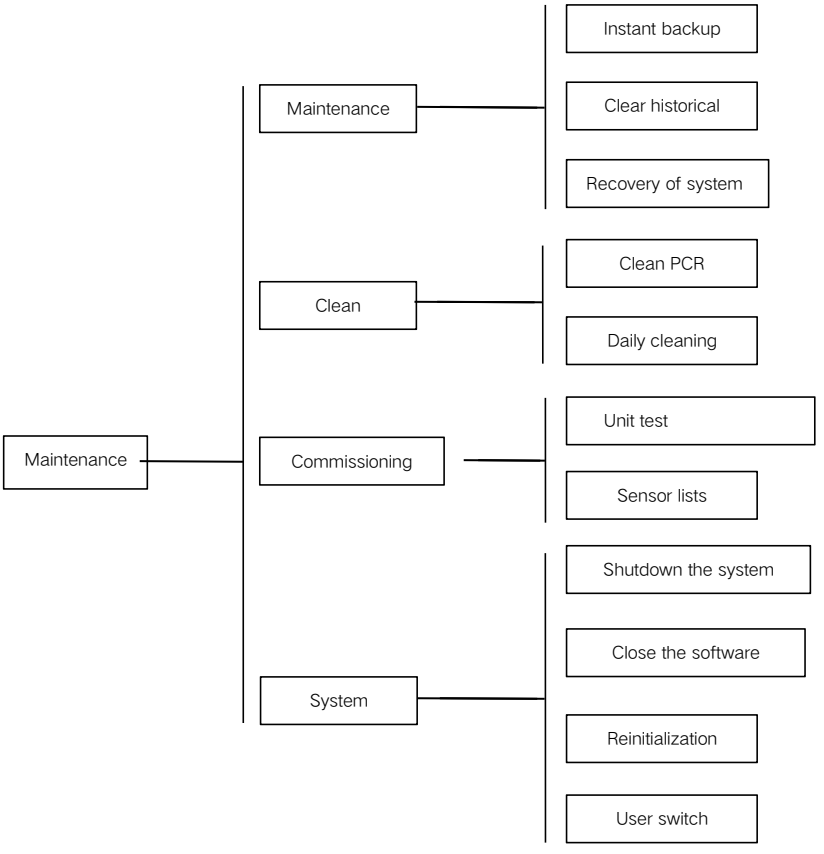
4.1.4.1 Test Analysis


Test analysis
Bulks
Consumables
Calibration
Calibration
Calibrator settings
QC
QC
QC settings
Test request
Patient test request
QC test request
Calibration test request
Test run
Request queue
In Process
Exception queue
Work Pending
Result analysis

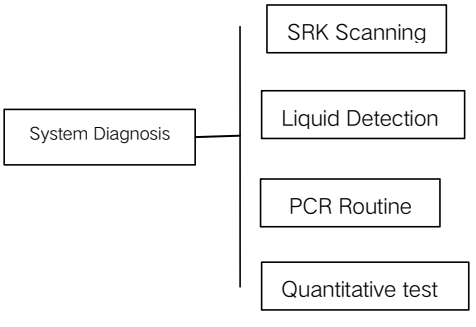
4.1.4.2 System Settings



4.1.4.3 Maintenance



4.1.4.4 System Diagnosis



4.2 Test Run

4.2.1 Request Queue

In the main interface menu, select Test Analysis to enter the Test Analysis wizard page interface, and select the “Request” button. The “Request” window displays the test requests that have been edited but the sample information that has not yet entered the sampling line.

Window Description:

Button Name	Description
Close	Exit the interface and return to the corresponding second-level navigation (detection, analysis, maintenance, diagnosis) interface; If you do not enter any secondary navigation interface before entering this interface, you will directly return to the main interface.
Find	Find the sample with the specified sample number
Edit Request	Switch to the interface corresponding to the selected sample to edit test request of the sample.
Test Result	Switch to test result management interface
Test Request	Switch to test request interface.

Find the sample.

Click the “Find” button to switch to the dialog box of “Find according to sample number”,

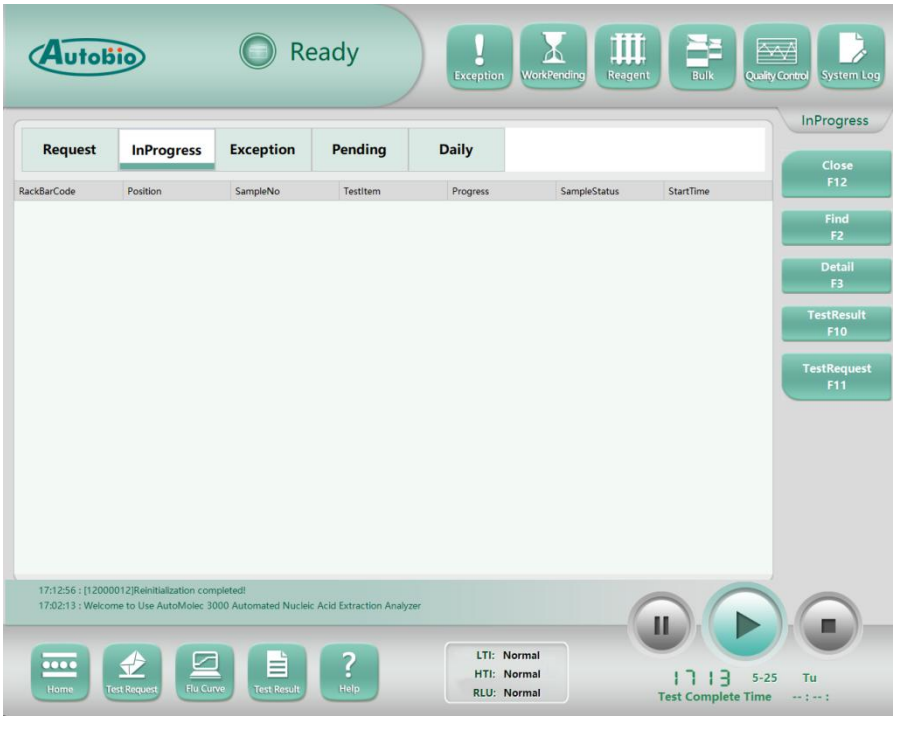
and enter the sample number you need to find to search.

Edit Request

Select the sample to be edited and click the "Edit Request" button to switch to the "Test Request" to edit the selected sample.

4.2.2 In Process

Select Test Analysis to enter the interface of the test and analysis wizard, then select the "In Process" button to enter into the interface . The "In Process" window displays the sample information that is currently being tested.

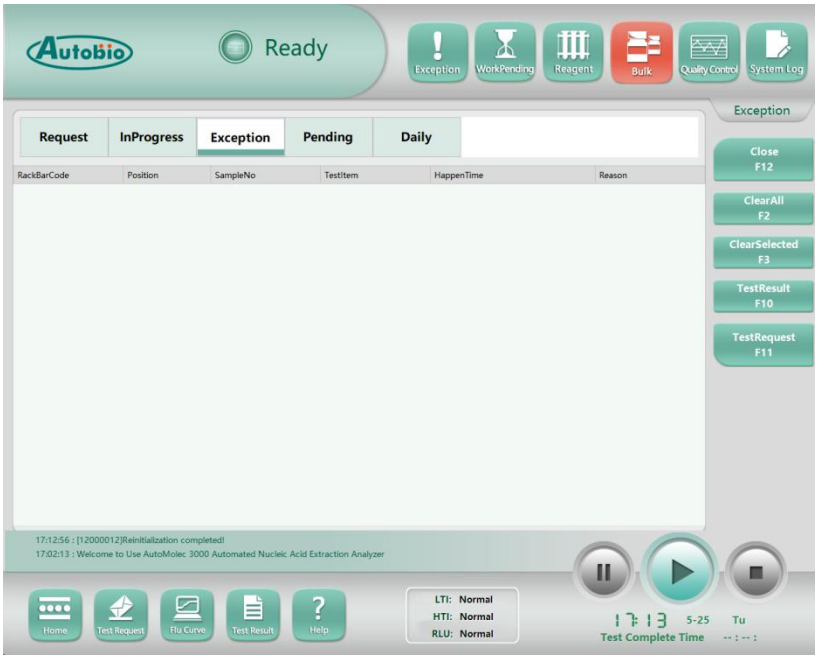


Window Description:

Button Name	Description
Close	Exit the interface and return to the corresponding second-level navigation (test, analysis, maintenance, diagnosis) interface; If you do not enter any secondary navigation interface before entering this interface, you will directly return to the main interface.
Find	Find the sample with the specified sample number
Details	Display the progress of the sample being tested on the instrument, etc
Test Result	Switch to test result management interface
Test Request	Switch to test request interface of the specified sample.

4.2.3 Exception Queue

Select Test Analysis to enter the interface of the test and analysis wizard, then select the "Exception" button to enter into the interface . The "Exception" window displays all test request information of abnormal samples.



Window Description:

Button Name	Description
Close	Exit the interface and return to the corresponding second-level navigation (test, analysis, maintenance, diagnosis) interface; If you do not enter any secondary navigation interface before entering this interface, you will directly return to the main interface.
Delete all	Delete all abnormal sample information tested
Delete the selected	Delete the abnormal sample information which is currently selected.
Test Result	Switch to test result management interface
Test Request	Switch to test request interface of the specified sample.

4.2.4 Work Pending

Select Test Analysis to enter the interface of the test and analysis wizard, then select the "Pending" button to enter into the interface . The "Pending" window displays all test request

information of samples in pending.

Window Description:

Button Name	Description
Close	Exit the interface and return to the corresponding second-level navigation (test, analysis, maintenance, diagnosis) interface; If you do not enter any secondary navigation interface before entering this interface, you will directly return to the main interface.
Delete all	Delete all samples in pending, including previously or currently edited samples.
Delete the selected	Delete the pending selected. Select the pending sample to be deleted, then click "Delete" button, the currently selected information of pending sample will be deleted.
Test Result	Switch to test result management interface
Test Request	Switch to test request interface of the specified sample.

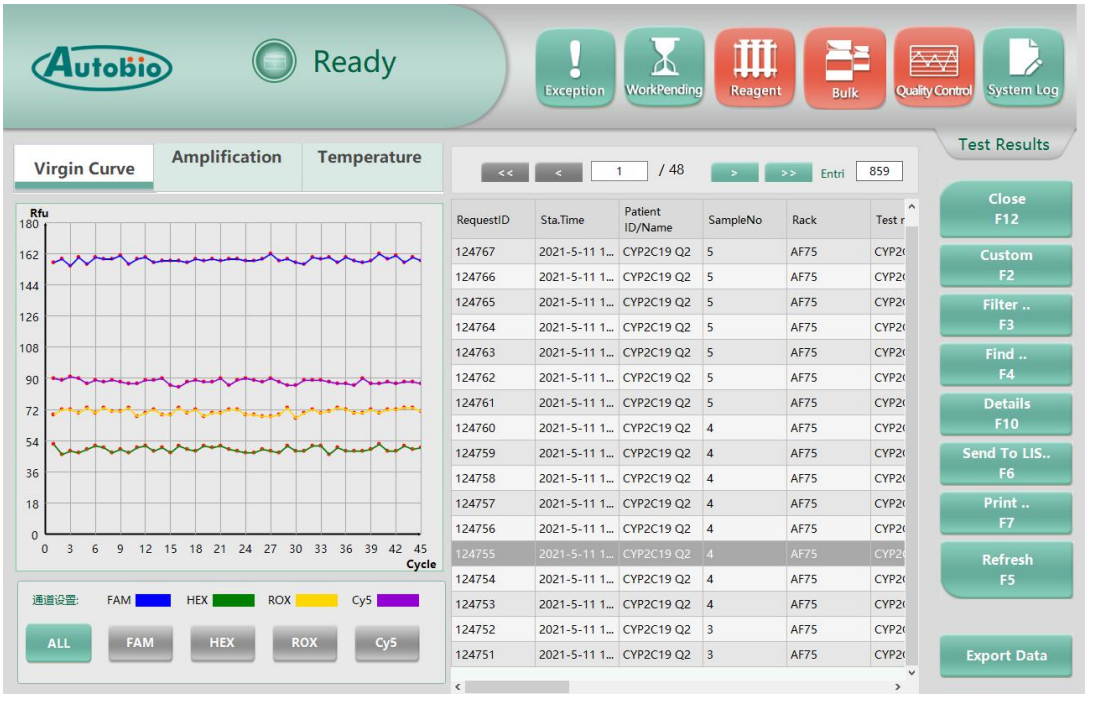
NOTE

Work pending displays the abnormal samples in the test, including "CLT" , "QNS" , "QNR"and "No Test";

If a pending occurs, the "Pending" button on the main interface flashes and appears yellow

4.3 Result Analysis

In the main interface menu, select test result to enter the test analysis - wizard interface, and select the corresponding button according to the test result data you need to display.



Window description:

Button name	Description
Close	Exit the interface and return to the corresponding second-level navigation (detection, analysis, maintenance, diagnosis) interface; If you do not enter any secondary navigation interface before entering this interface, you will directly return to the main interface.
Custom Display Item	Select the display items of test results and customize the display order.
Filter	Set up filtering conditions, and filter test result data.
Find	Find the record for the specified condition in the screened test result.
Detailed Information	Display the detailed information contained in the test.
Sent to the LIS	Sent the test results to the LIS system.
Print	Print out the test result data.

Refresh	Refresh the current detection result.
Export	Export the test result information for the selected test.

4.3.1 Custom Display Item

You can set the item information you want to display by yourself. Click the button of "Customize", select the items to be displayed and the display order in the pop-up display customization setting box, and click "OK" to display the test result according to the customization setting.

4.3.2 Filtering Test Results

Click the "Filter" button to enter the screening condition setting interface. You can select the existing screening condition or create a new screening condition. After setting the screening condition, click "OK" to screen the detection result according to the set condition.

4.3.3 Find Detection Results

Click the "Find" button after screening the detection results, and click the search button after setting the search criteria to find the detection results.

4.3.4 View Detailed Information

Select the test result that you want to view the details, click the "Details" button, and the details of the selected test result can be viewed in the details window that pops up.

4.3.5 Sent the Test Results to the LIS System

Select the detection results to be sent, and click "Send to LIS" button to send the detection results to LIS system.

4.3.6 Print Test Results

You can print the test result data in the form of report. Click the "Print" button to print the test result into a report. Please refer to the report description section for the report format.

4.3.7 Refresh Test Results

You can update the test results to the latest status by clicking the "Refresh" button.

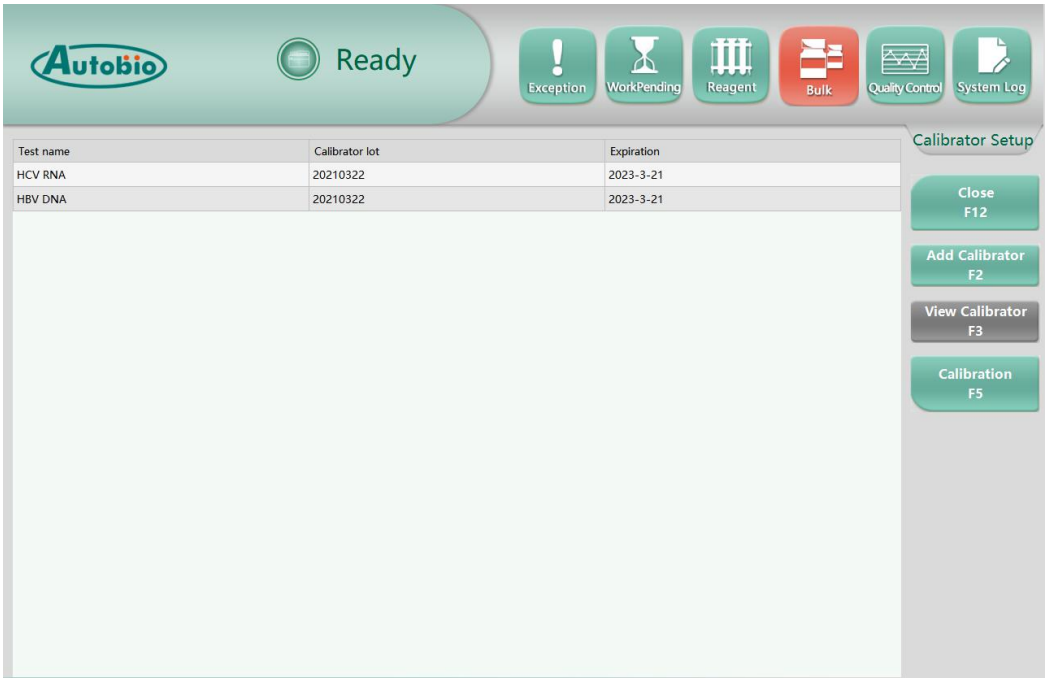
4.3.8 Export Test Results

You can export the test result information for the selected test to an Excel document.

4.4 Calibration

4.4.1 Calibrator Setup

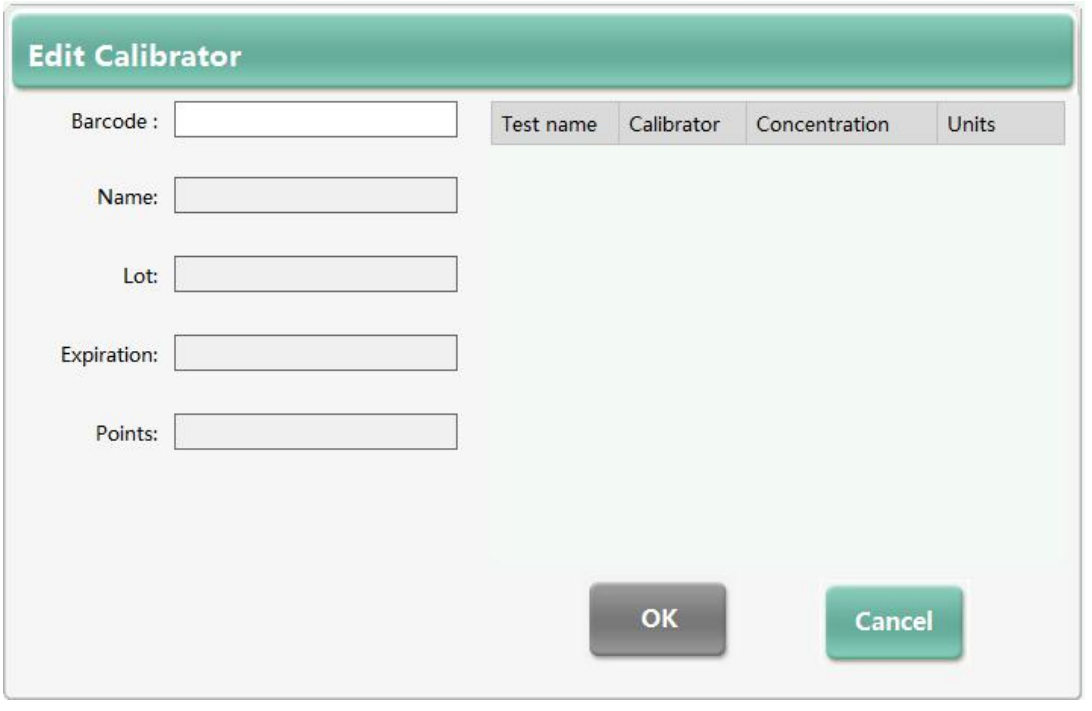
In the main interface menu, select test analysis to enter the test analysis - wizard interface, and select “Calibrator Setup” to enter the corresponding interface.



Window description:

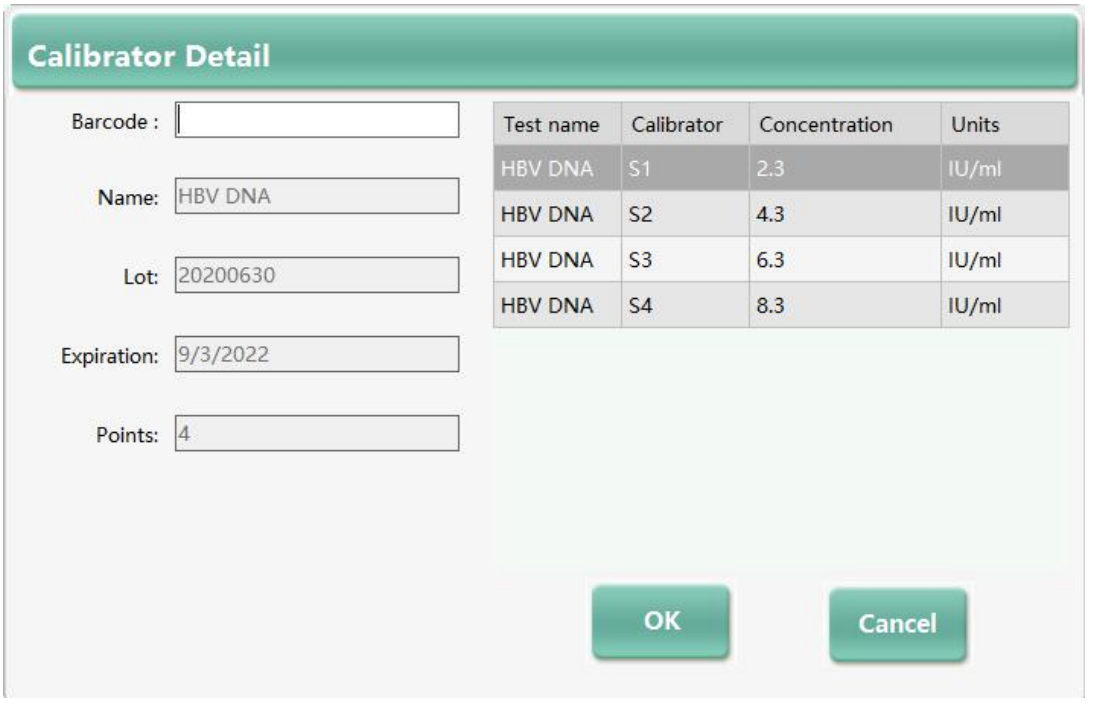
Button name	Description
Close	Exit the interface and return to the corresponding second-level navigation (detection, analysis, maintenance, diagnosis) interface; If you do not enter any secondary navigation interface before entering this interface, you will directly return to the main interface.
Add Calibrator	Click it and the “Add New Calibrator” dialog box will pop up.
View Calibrator	Select the calibrator, and click it to pop up the selected calibrator details dialog box. If the calibrator is not selected, the button will not be available.
Calibration	Go to the calibration results view interface.

4.4.1.1 Add Calibrator



1. Click the “Add calibrator” button to switch to the “Add new calibrator” dialog box.
2. Scan the barcode of the calibrator.
3. Select the OK button.

4.4.1.2 View Calibrator



1. Select the calibrator to be viewed, click the button to view calibrator, and switch to the dialog box of calibrator details.

4.4.2 Calibration Tests

4.4.2.1 Enter the Calibration Request Interface

In the main interface menu, select test analysis to enter the test analysis - wizard interface, and select “Calibration Test Request” to enter the calibration request interface.

CAUTION:

1. Each module contains at most 5 samples, and a set of calibration test requests contains at most 15 standards, therefore, three sample racks may be added for calibration detection.
2. In the selection of calibrator, only calibrator of which batch is same to the corresponding reagent is allowed.

Window description:

Name	Description
Sample rack no.	Click “?” with the mouse to activate the sample rack input box.
Position	Regular automatically number from 1 to 5.
Calibrator	Calibrator names are permanently marked with S1 - S15.
Test times	The number of tests can be modified. The number of qualitative tests is 1-3, and the number of tests for each standard can be set separately. The quantitative detection times are 1-2 times, and the detection times of all standard products must be equal; The number of qualitative test and quantitative test for each standard product is default 1.
Item name	Identify markers for each item.
Batch No.	Production date of reagents.
Expiration	Expiry date of the reagent.
Remaining times	Remaining times of the reagent usage.
Close this window	Exit the interface and return to the corresponding second-level navigation (detection, analysis, maintenance, diagnosis) interface; If you do not enter any secondary navigation interface before entering this interface, you will directly return to the main interface.
Increase times	Click the button once, and the number of tests of the currently selected standard product is increased by 1.
Decrease times	Click the button once and the number of tests of the currently

	selected standard product will be reduced by 1.
Select the calibrator	Add the standards information contained in the currently selected project to the sample rack.
Delete	Delete the current sample rack and the sample information it contains. If the sample rack number does not exist, the button is not available.
Save	Save the added standards information to the system, and the added new calibrator must be saved before testing.

4.4.2.2 Add Sample Rack and Standards

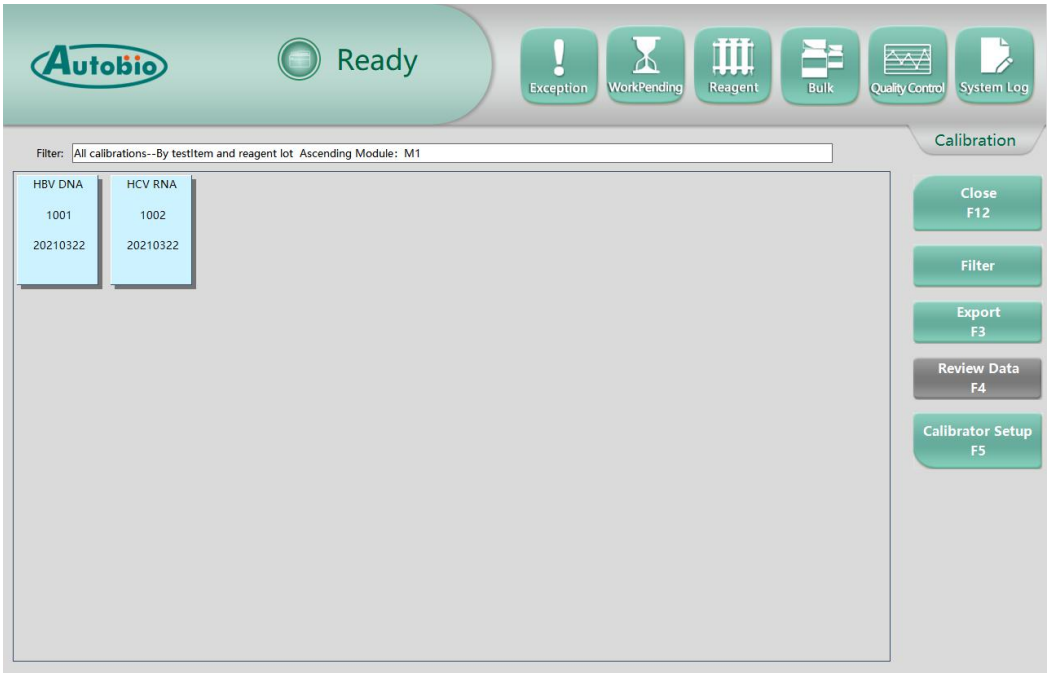
1. Put each standard packaging container into the sample rack according to its serial number.
2. Select the calibrator used in this calibration in the calibrator list box.
3. Select the "Select Calibrator" button.
4. Scan or input the sample rack bar code used in this calibration.

4.4.2.3 Edit the Calibration Test Request

1. Scan or input the first sample rack bar code in the sample rack calibration request that needs to be edited.
2. Select the project name and batch number of the project in the reagent selection list box.
3. Select the calibrator used in this calibration in the calibrator list box.
4. Select the “Select Calibrator” button.
5.Scan or enter the bar code of the sample rack used in this calibration.
6. Click the “Save” button on the right to save the calibration test edited to the database.

4.4.2.4 Calibration Results

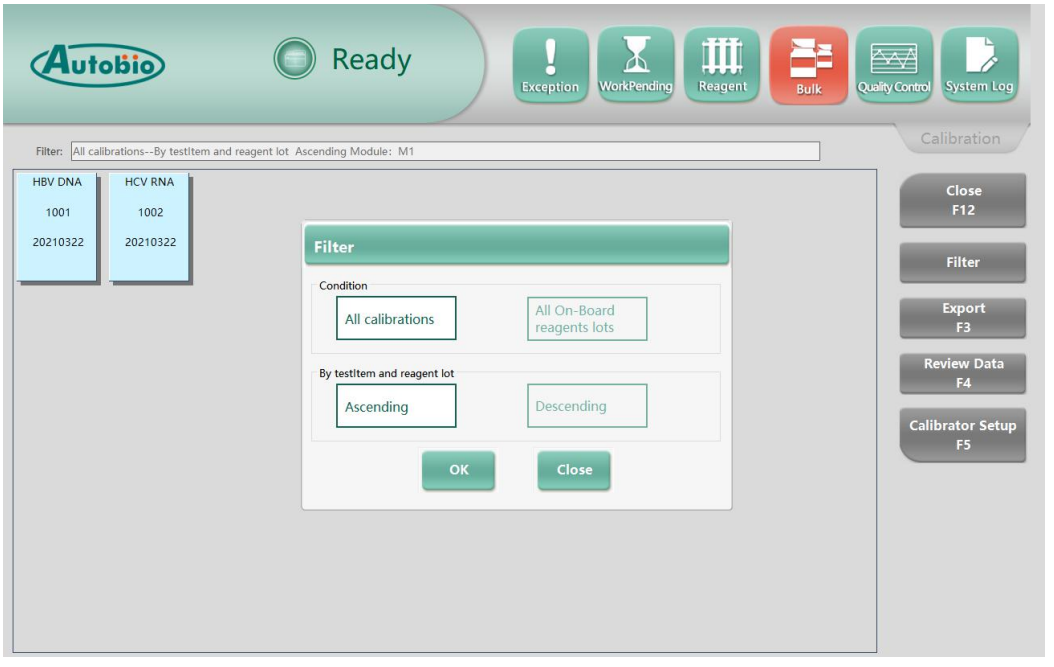
In the main interface menu, select the detection analysis to enter the detection analysis - wizard interface, and select the "Calibration" button to switch to the calibration management window to view the calibration results generated after the detection is completed.



Window description:

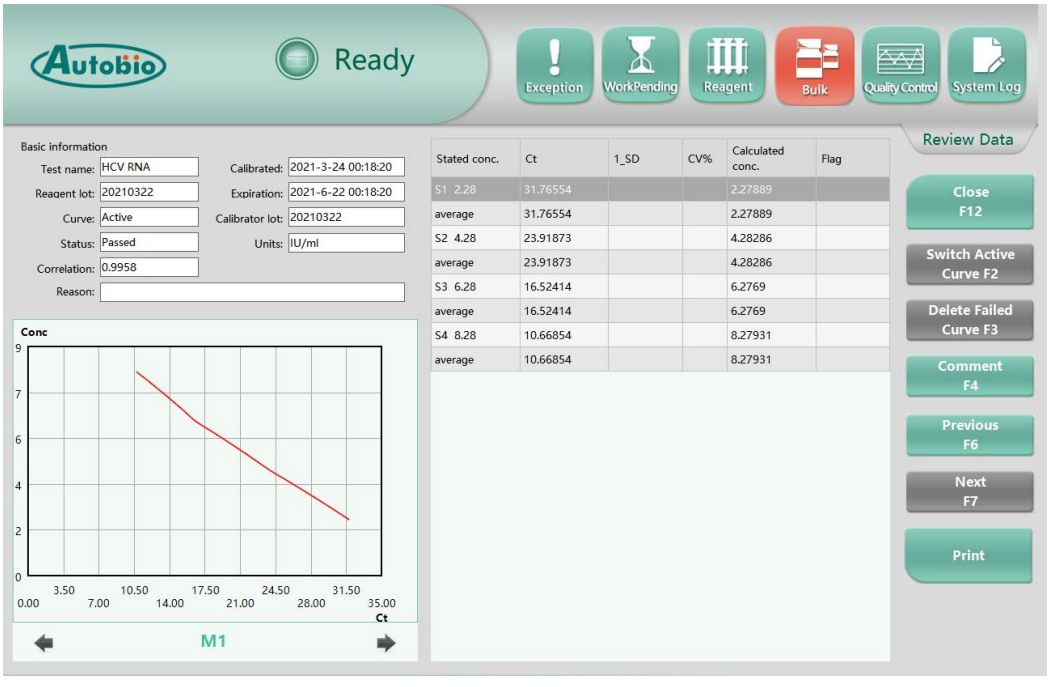
Button name	Description
Close this window	Exit this interface.
Filter	Select and manage the calibration results according to the set conditions.
Review Data	View the detection data and calibration curves contained in the selected calibration results.
Calibrator Setup	Switch to the calibrator setup interface.

4.4.2.5 Filter



1. Enter the filtering management interface, click the screening button, and the screening condition setting box pops up.
2. Select the filtering criteria.
3. Select the sorting method.
4. Select the OK button.

4.4.2.6 Review Data



Select the calibration that needs to review data, and click the "Review Data" button to switch to the result data review interface, which mainly includes basic calibration information, calibration data and calibration curve.

Window description:

Name	Description
Basic Calibration Information	1. Basic information includes "Test Name", "Reagent Batch Number", "Calibration Time", "Calibration Validity Period" "Unit",, "Calibration Curve", "Status", "Reason", "Calibrator Batch Number" and "Correlation Coefficient"., "Reason". 2. The calibration time is the time when the calibration test is completed, and the calibration expiration is the calibration time and the effective days of the calibration (this parameter is set in the calibrator setup interface). 3. The calibration curve displays contents including "Active" and "Inactive". 4. The status display includes "Passed" and "Failed". 5. The reason display includes "Insufficient Data", "HCV", "Not Fit".
Calibration Data	1. Calibration result data includes "Specified Concentration", "CT", "1_SD", "CV %", "Calculated concentration" and "flag concentration".

	2. Display the test result value of the two test standards, the average value of the specified concentration of these two values, the average value of the calculated concentration, 1_SD, and CV % in different rows respectively. 3. If the calculated concentration does not have data, it will display "No Value".
Calibration Curve	Draw the curve according to the standard substance concentration and RLU value. The X-axis represents the concentration value, and the Y-axis represents the Ct value. The minimum and maximum values of the X-axis are 0 and 45 The calibration curve is drawn according to the fitting curve of the item. Qualitative items have no calibration curve.
Close	Exit this interface and return to the calibration management interface.
Convert the Activated Calibration Curve	Select the current calibration curve as the activated calibration curve.
Delete the Curves that fail validation	Delete calibration curves that fail validation.
Note	Add a comment to the current display calibration curve.
Print	Print the current calibration results (calibration basic information, calibration data, calibration curve).
	Go to the previous curve.
	Go to the next curve.

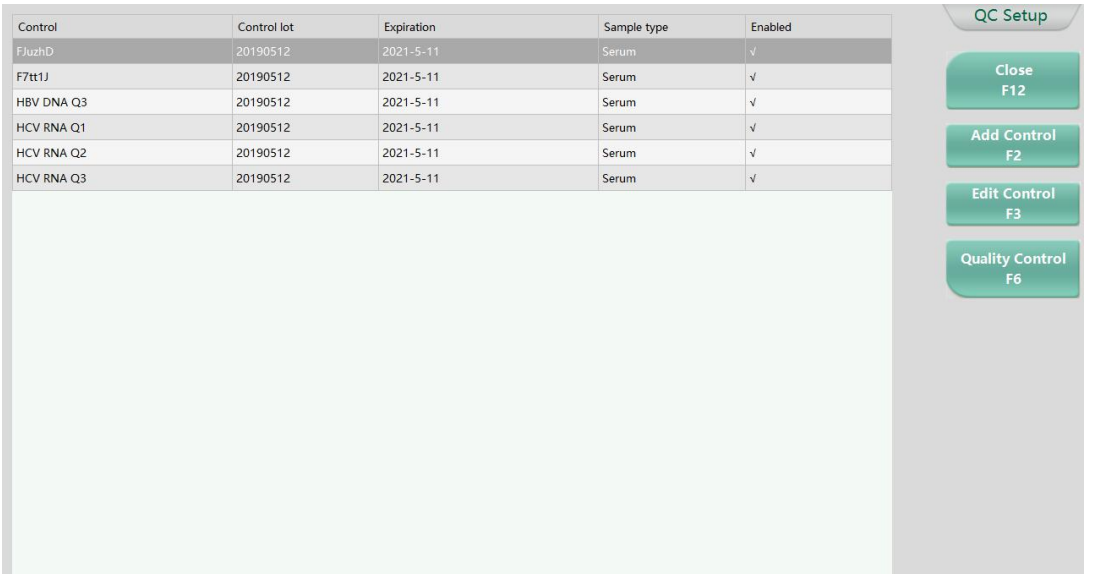
Note: If the reagent batch number is changed or the expiration of the calibration is exceeded, the calibration test shall be conducted again. If the calibration test is not conducted again, the test result may be inaccurate or misjudged.

4.5 Quality Control

Quality control is an important means to verify the validity of calibration curve. Calibration curves will become void after being used for a period of time because of machine wear or other factors. Through analyzing the quality control test results, the purpose of verifying the validity of calibration curve is achieved.

4.5.1 Quality Control

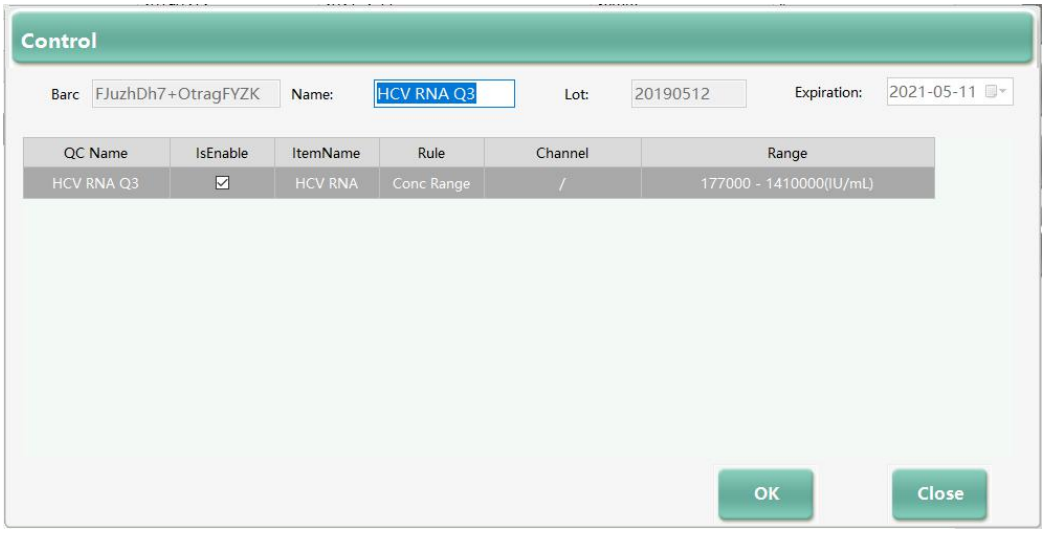
In the main interface menu, select the test analysis to enter the test analysis - wizard interface, and select the “QC Setup” in the quality control to enter the quality control settings interface for quality control management settings.



Window description:

Button name	Description
Close	Exit this interface.
Add Control	Add new quality control to the system.
Edit Control	Edit the currently selected quality control data.
Delete Control	Delete the added quality control.
Quality Control	Enter the quality control interface.

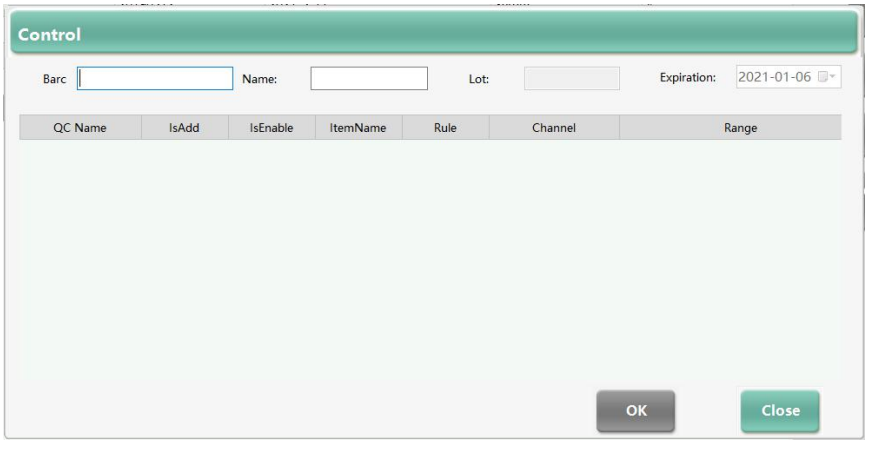
4.5.1.1 Add Quality Control



1. Enter the quality control setting interface, select "Add Quality Control" button, and switch to the "Add Quality Control Information" dialog box.
2. By scanning the barcode card of quality control products with the barcode scanner, the system can parse the barcode information into quality control products and quality control rule information, which is displayed in the table below.
3. If the name of quality control product needs to be modified, click to select the corresponding line of quality control product and modify it in the above quality control product column.
4. You can choose whether to add the specified quality control products to the system.
5. You can also choose whether or not to enable the specified quality control to be enabled in the system.
6. Select “OK” button.

4.5.1.2 Edit Quality Control

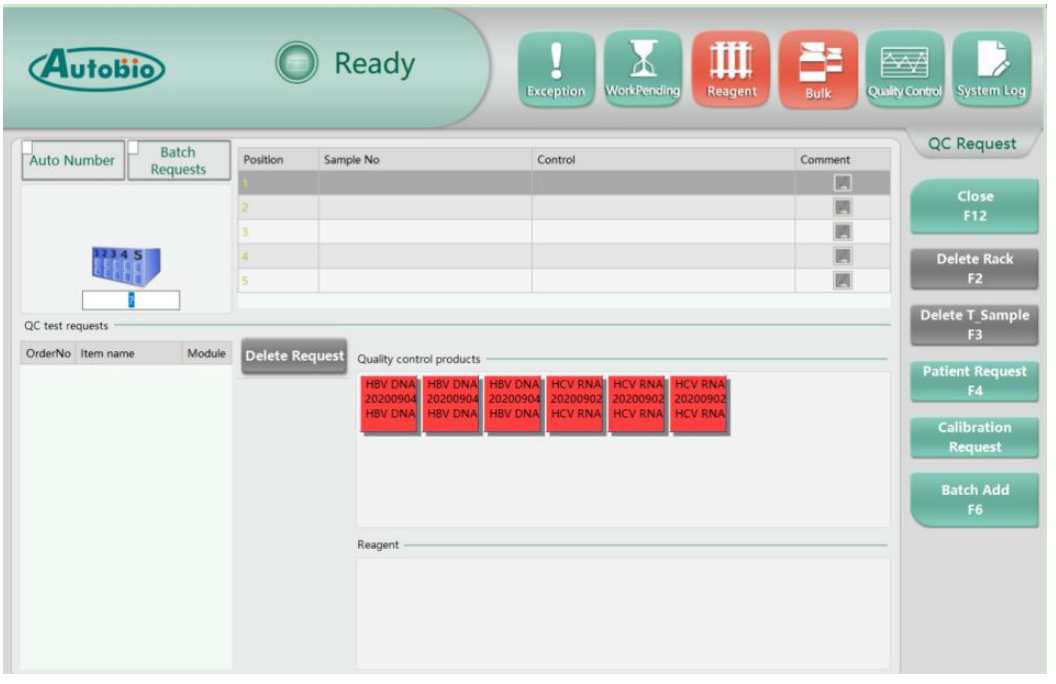
1. Select the quality control to be edited in the quality control settings window.



2. Modify the name of quality control.

3. Select "OK" button.

4.5.2 Quality Request



Window description:

Button name	Description
Close	Exit this interface.
Delete Rack	Delete the sample rack that has been added, including samples and tests of the sample rack.
Delete Sample	Delete the selected sample, including the tests it contain.
Patient Request	Skip to the patient detection request interface.
Calibration Request	Skip to the calibration request interface.
Batch Add	For mixed quality control samples, multiple tests can be added in batch.

4.5.2.1 Quality Control Request

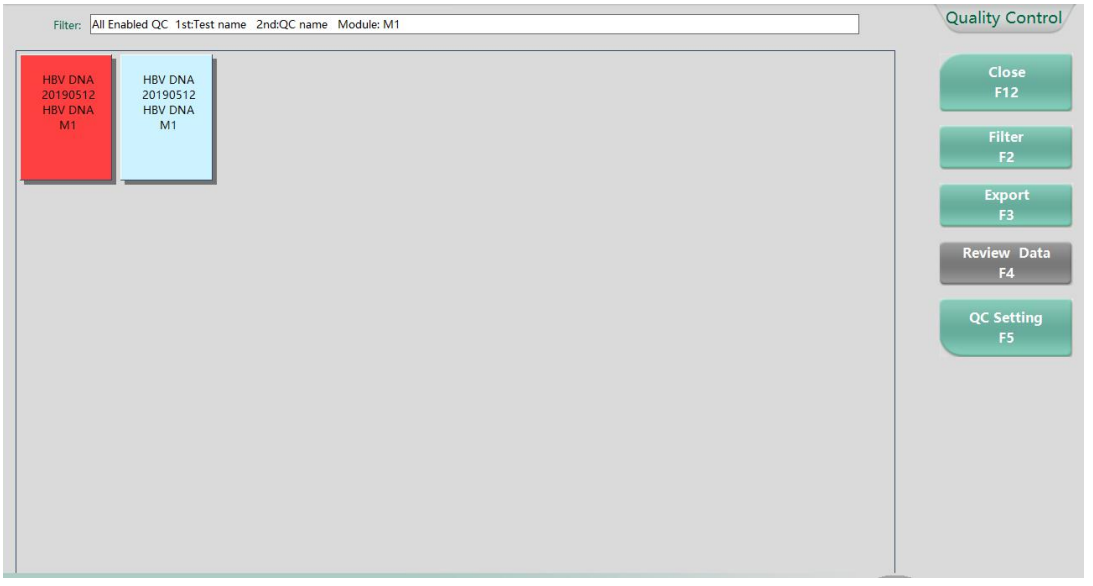
1. Enter the interface of quality control request.

2. Scan or input the calibration request for the first sample rack barcode to be edited in the sample rack bar code frame.

3. According to the position of quality control samples in the module, select the corresponding position in the sample input list box.

4. Select quality control test items and add quality control test request.

4.5.2.2 Quality Control Results



In the main interface menu, select detection and analysis to enter the interface of detection and analysis - wizard, and select the "Quality Control" button to switch to the quality control management window to see the quality control result data generated after the completion of quality control detection.

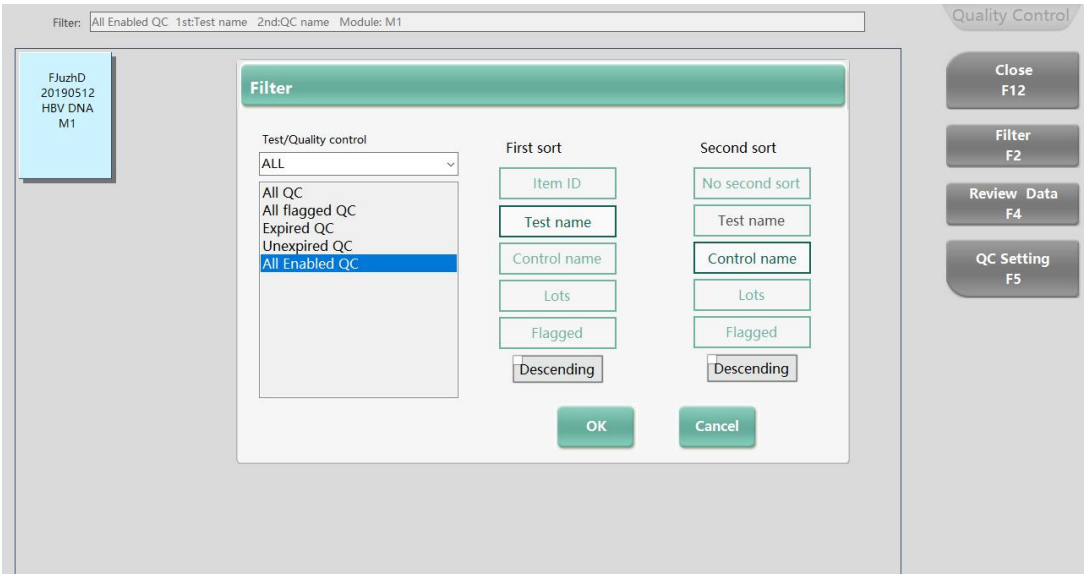
NOTE

When the quality control results are normal, the background color will be light blue. If the latest test result of quality control product is out of control, the background will be red.

Window description:

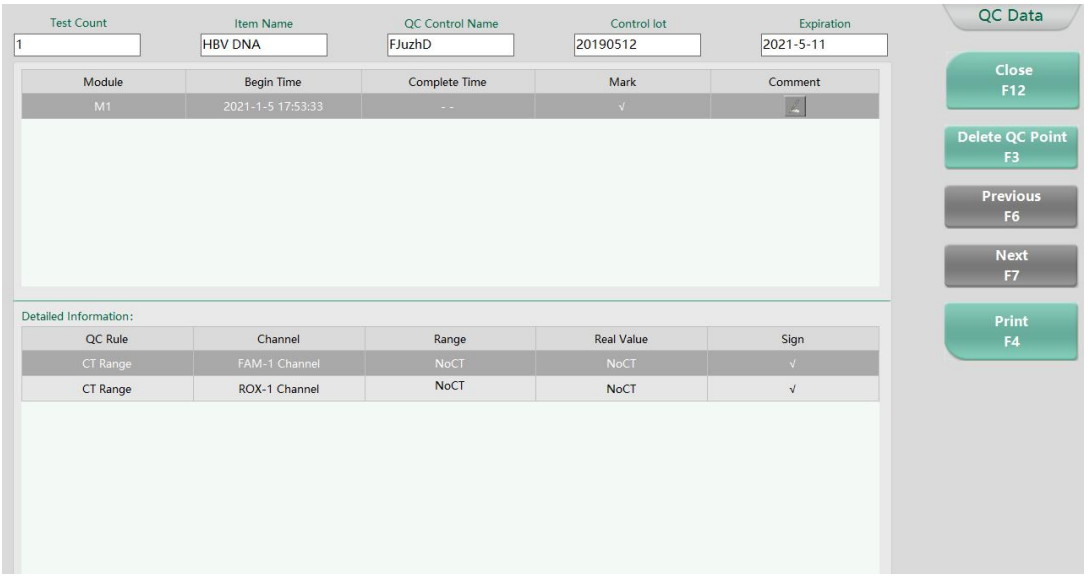
Button name	Description
Close	Exit the interface and return to the corresponding second-level navigation (detection, analysis, maintenance, diagnosis) interface; If you do not enter any secondary navigation interface before entering this interface, you will directly return to the main interface.
Filter	Filter and manage the quality control results according to the set conditions.
Review QC Data	View the test result data of selected quality control, and the button is not available if no quality control result is selected.
QC Setting	Click the button to switch directly to the interface of quality control setting.

4.5.2.3 Quality Control Results Filter



1. In the quality control management interface, select the "Filter" button to switch to the filter dialog box.
2. Select the filter criteria.
3. Select the sorting method.
4. Select “OK” button.

4.5.2.4 Review QC Data



Select the quality control to be reviewed, and click the "QC Data" button to switch to the review window of QC data.

Window description:

Name	Description
Basic Information of QC	1. 1. Basic information of quality control: "Number of items", "Test", "Quality control", "Batch number of Quality control", "Validity period"; 2. Test basic information; 3. Detailed information of quality control rules.
Close	Exit this interface and return to the calibration management interface.
Delete QC Point	Delete the currently selected quality control test.
Previous	Check the previous quality control data.
Next	Check the next quality control data.

1. Screening quality control test: Click the table above to select different quality control test, and the detailed quality control rules of the test can be seen below.

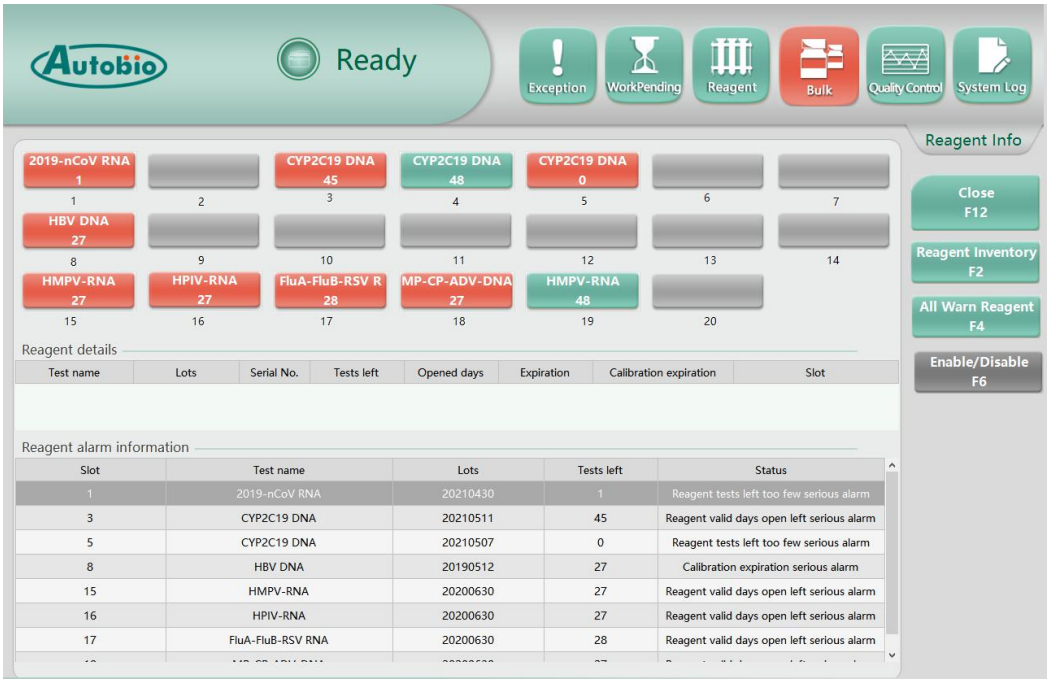
2. Quality control point note: The quality control result data can be annotated. If the data point has been annotated, the "note" button displays a text icon. If no note is added, the note button displays a pen icon.

Note: It is necessary to carry out the quality control test at the same time during the daily test to observe whether the quality control is under control. If the quality control test is not conducted, the test result cannot be proved to be accurate.

4.6 Consumables

4.6.1 Reagent Information

On the main interface menu, select “Test Analysis” to enter the test and analysis secondary navigation interface. Select the “Reagent Info” button to enter the reagent information interface: the slot number, reagent name and tests left on the machine can be viewed. Select a reagent on the instrument and view the reagent details list: test name, lots, serial number, tests left, opened days, Expiration, and calibration expiration(Quantitative/semi-quantitative items: display specific date; qualitative/typing items: display "--"), slot location and other information; If the selected reagent has a warn, check the following information in the Reagent Alert List: slot, test names, lots , tests left and status.

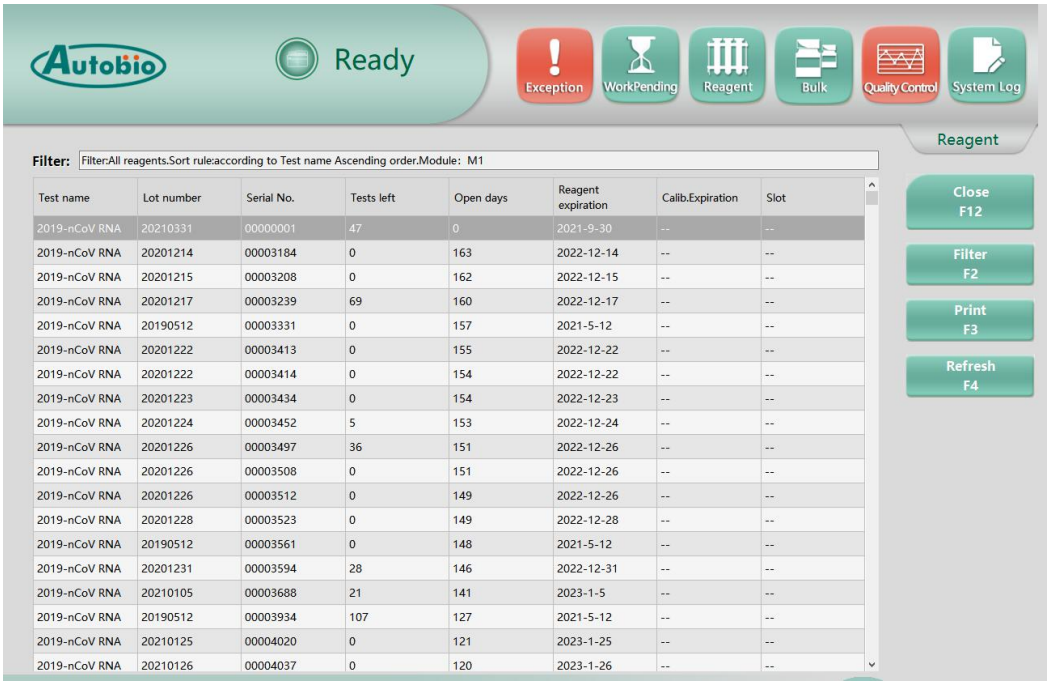


Window description:

Button Name	Description
Close	Exit this interface and return to the corresponding secondary navigation (test analysis) interface.
Reagent Inventory	Switch to the kit list management interface.
All Warn Reagent	All reagent warnings are displayed in the list of reagent warnings below the reagent warnings interface on the instrument.
Enable/Disable	Enable and disable the selected reagent.

4.6.1.1 Kit List

In the all warn reagent interface, select the "Reagent Inventory" button to enter the reagent detail list management interface.



Test name	Lot number	Serial No.	Tests left	Open days	Reagent expiration	Calib.Expiration	Slot
2019-nCoV RNA	20210331	00000001	47	0	2021-9-30	--	--
2019-nCoV RNA	20201214	00003184	0	163	2022-12-14	--	--
2019-nCoV RNA	20201215	00003208	0	162	2022-12-15	--	--
2019-nCoV RNA	20201217	00003239	69	160	2022-12-17	--	--
2019-nCoV RNA	20190512	00003331	0	157	2021-5-12	--	--
2019-nCoV RNA	20201222	00003413	0	155	2022-12-22	--	--
2019-nCoV RNA	20201222	00003414	0	154	2022-12-22	--	--
2019-nCoV RNA	20201223	00003434	0	154	2022-12-23	--	--
2019-nCoV RNA	20201224	00003452	5	153	2022-12-24	--	--
2019-nCoV RNA	20201226	00003497	36	151	2022-12-26	--	--
2019-nCoV RNA	20201226	00003508	0	151	2022-12-26	--	--
2019-nCoV RNA	20201226	00003512	0	149	2022-12-26	--	--
2019-nCoV RNA	20201228	00003523	0	149	2022-12-28	--	--
2019-nCoV RNA	20190512	00003561	0	148	2021-5-12	--	--
2019-nCoV RNA	20201231	00003594	28	146	2022-12-31	--	--
2019-nCoV RNA	20210105	00003688	21	141	2023-1-5	--	--
2019-nCoV RNA	20190512	00003934	107	127	2021-5-12	--	--
2019-nCoV RNA	20210125	00004020	0	121	2023-1-25	--	--
2019-nCoV RNA	20210126	00004037	0	120	2023-1-26	--	--

NOTE

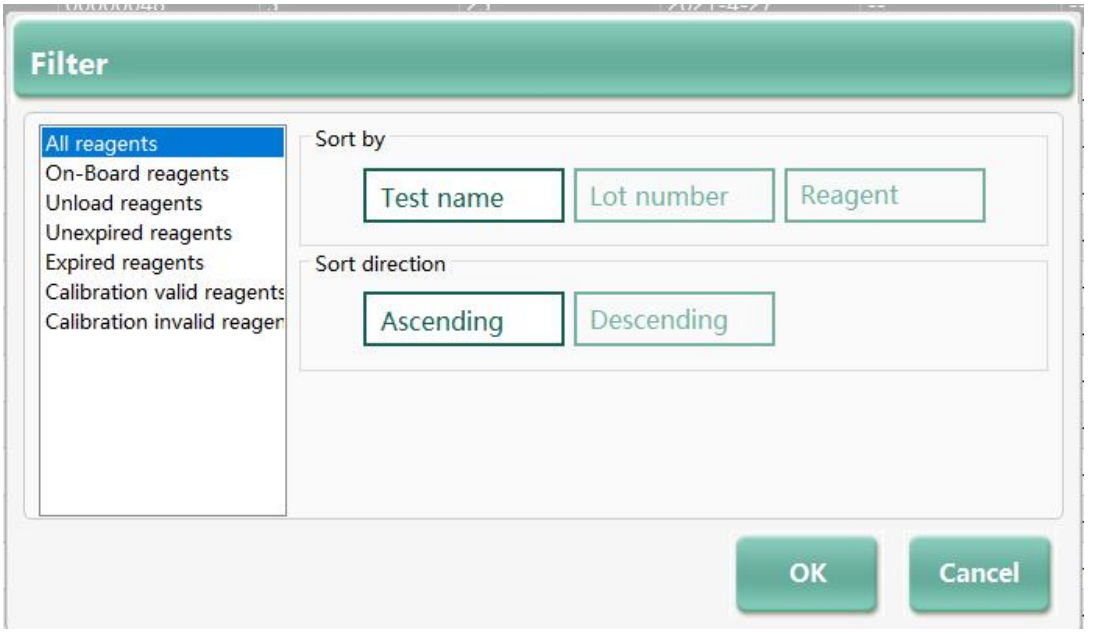
1. When the reagent has been unloaded, display "--" in the slot field.
2. If the reagent has expired or the calibration period is expired, the text will be displayed in red.

Window description:

Button Name	Description
Close	Exit this interface and return the corresponding secondary navigation (detection, analysis, maintenance, diagnosis) interface. If you enter this interface directly from the main interface, you will directly return to the main interface.
Filter	Set the screening criteria and record the screening kit according to the criteria.
Print	Print the list of selected reagents and the information it contains.
Refresh	Refresh all kits information.

4.6.1.2 Filtering Kits List

1. Select the “Filter” button to switch to the filter condition setting dialog box.



2. Select the filter criteria.

3. Select the sorting basis.

4. Choose the sorting direction.

5. Select “OK” button.

4.6.1.3 Change Reagent Online

During the test run, if it is found that the number of reagents remaining in the test item is insufficient, open the reagent bin gate and insert the new kit that needs to be supplemented into the empty reagent tank. After the kit is inserted, the relevant information of the newly inserted kit can be displayed on the reagent information interface by reading the RFID information of the kit.

CAUTION:

Do not pull out the reagent strip in use. After pulling out, if the reagent does not exist on the slot when adding the reagent, it will cause the instrument to stop urgently!

4.6.2 Consumables

1. The status and details of PCR tubes are shown at the left column of the figure above.

2. The status and details of the reagent probe tip are shown at the middle column of the figure above.

3. The status and details of strip are shown at the top right of the figure above.

4. The status of purified water container is shown in the center right of the figure above.
5. The status of the waste liquid tank is shown at the bottom right of the figure above.
6. The status of solid waste bin is shown at the bottom of the figure.

Window description:

Button Name	Description
Close	Exit this interface and return the corresponding secondary navigation (detection, analysis, maintenance, diagnosis) interface. If you enter this interface directly from the main interface, you will directly return to the main interface.
Clean Solid Waste	Replace the garbage bags in the waste bin where the scrap card and TIP and PCR tubes are placed on the instrument.

WARNING

In these processes, you will come into contact with potentially infectious materials. Please handle and dispose these biologically hazardous materials in accordance with proper

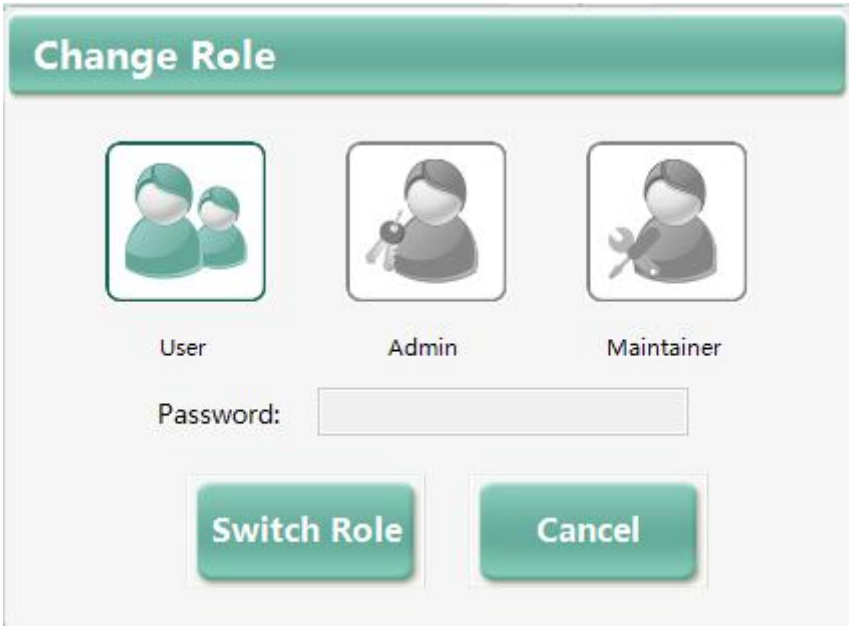
laboratory procedures. The hand, eyes and face must be properly protected.

Note: TIP and PCR tubes are disposable consumables and cannot be reused.

4.7 System Settings

Prompt: System Settings require the operator to have administrator privileges.

The default role of system login is operator, so the administrator password must be entered when entering system settings. When the role is switched to administrator, no password authentication is required to enter system settings.



System settings interface description:

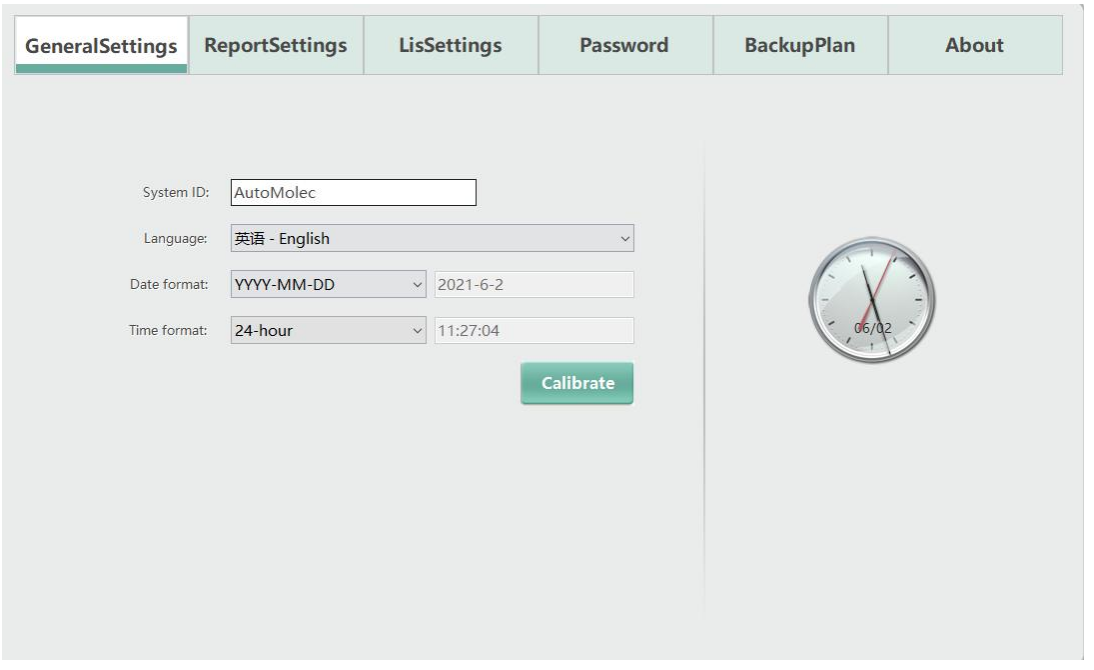
Item	Description
General Settings	General settings include system identity, date format, time format, system language.
Report Settings	Set the system header information, printer selection, and report configuration in the print report.
LIS Settings	Set LIS communication parameters.
Password	Change the administrator password.
Backup Plan	Set data backup conditions.
About	Display system version information.

1. After completion of the settings, click “Save F2” and the settings will take effect.

2. To cancel, click [Close this window F12].

4.7.1 General Settings

Enter the system settings interface, and the default open option is the interface of general settings.



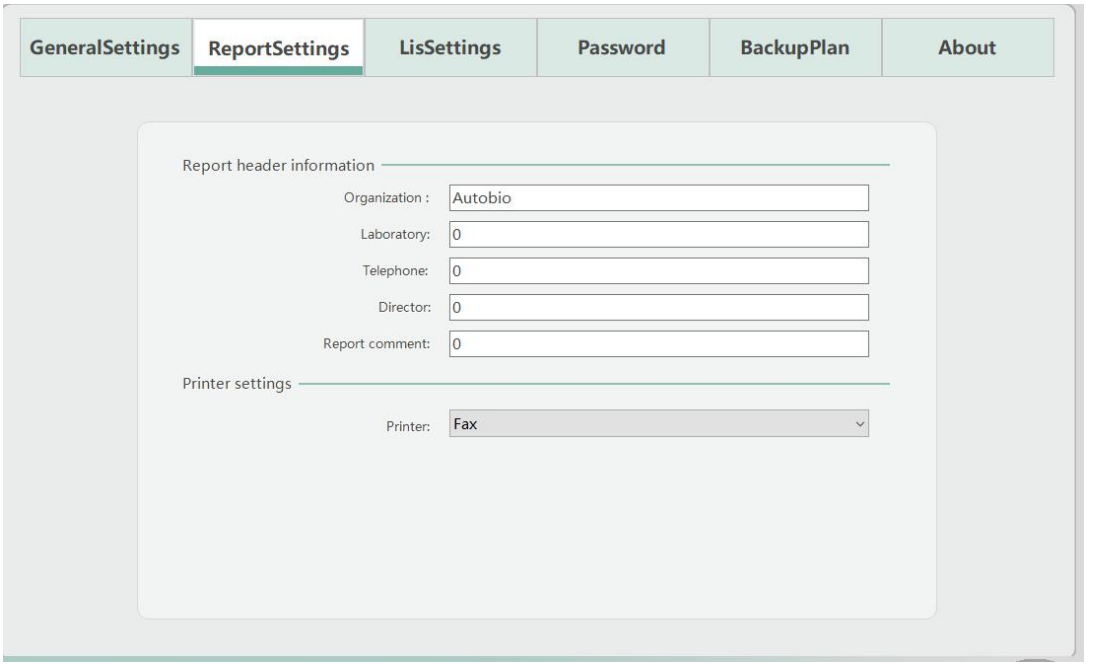
General settings interface description :

1. After the settings are completed, click “Save F2” and the settings will take effect.

2. To cancel, click [Close F12].

Item	Description
System ID	1-12 characters can be entered as remarks, and the software has no special requirements.
Language	Options for setting system language include: Chinese (Implified, PRC)-Chinese (Simplified, PRC), English-English
Date Format	Options for date format settings include (YYYY/MM/DD, YYYY.MM.DD, YYYY-MM-DD, MM/DD/YYYY, MM.DD.YYYY, MM-DD-YYYY)
Time Format	Options for the time format settings include 24-hour and 12-hour.
Calibrate	Calibrate the time information currently displayed.

4.7.2 Report Settings

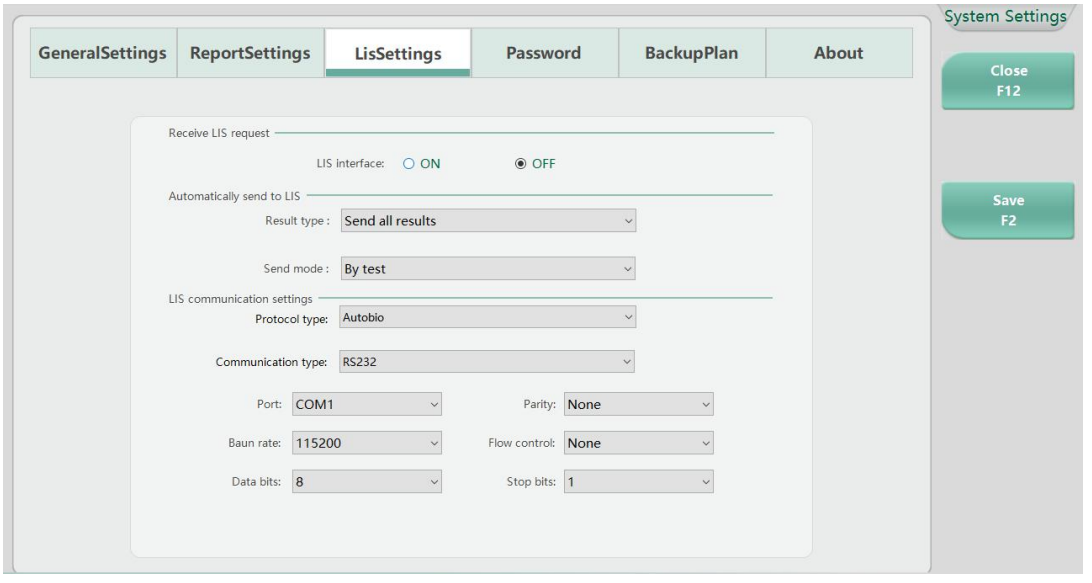


Report settings interface description:

Item	Description
Organization	Organization name settings
Laboratory	Laboratory name settings
Telephone	Tel settings
Director	Enter director's name
Report Comment	Enter the remark information of test report
Printer	Select printer
Report	Select the report type. If you need to change the report, click format adjustment to make changes.
Format Settings	The format of the report can be adjusted according to the need.

1. After the settings are completed, click "Save F2" to take effect.
2. If it is anticipated to cancel, click [Close this window F12].

4.7.3 LIS Settings



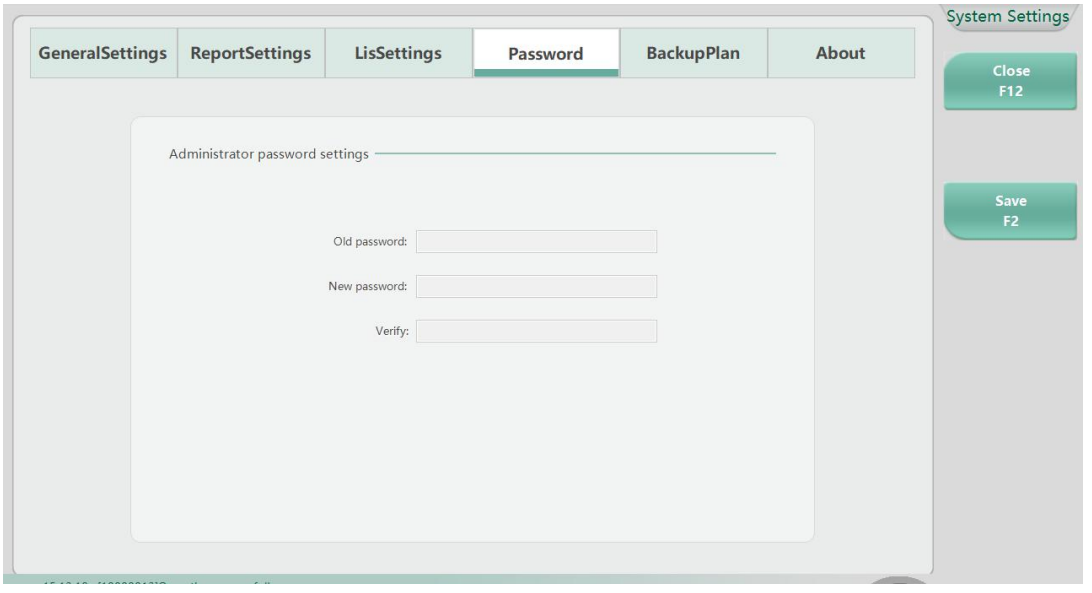
LIS communication parameter settings interface description:

Item	Description
LIS Interface [Open]	Open the LIS communication port
LIS Interface [Close]	Close the LIS communication port
Results Categories	Include (send all results, none)
Send Mode	LIS sending mode settings, including (by test, by sample)
Protocol Type	Selection of communication protocol types (Autobio Protocol, H7L Protocol)
Communication Types	Communication types (RS232, network port)
Port	Set LIS communication port
Baud Rate	Set LIS communication baud rate
Data Bits	Set LIS communication data bits
Odd-even Check	Set LIS communication parity check parameters
Flow Control	Set LIS communication flow control
Stop Bit	Set LIS communication stop bit

1. After the settings are completed, click “Save F2” to take effect.

2. If it is anticipated to cancel, click [Close F12].

4.7.4 Administrator Password



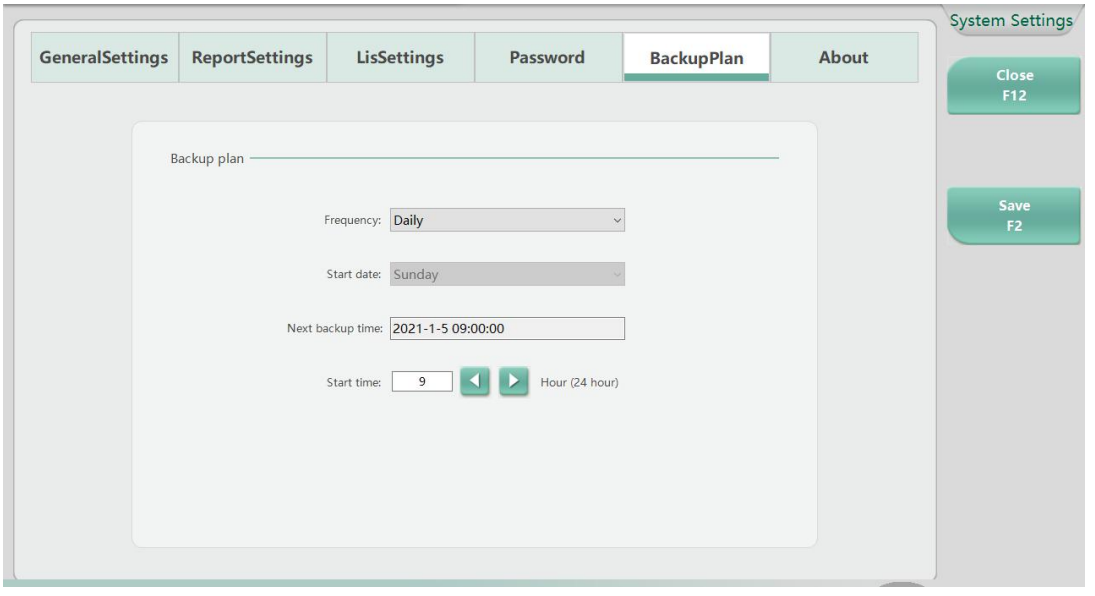
Administrator password interface description:

Item	Description
Old Password	Enter the administrator's old password.
New Password	Enter the new password that the administrator wants to change.
Verify	Re-enter the new password that the administrator wants to change.

1. After the settings are completed, click “Save F2” to take effect.

2. If it is anticipated to cancel, click [Close this window F12].

4.7.5 Backup Plan



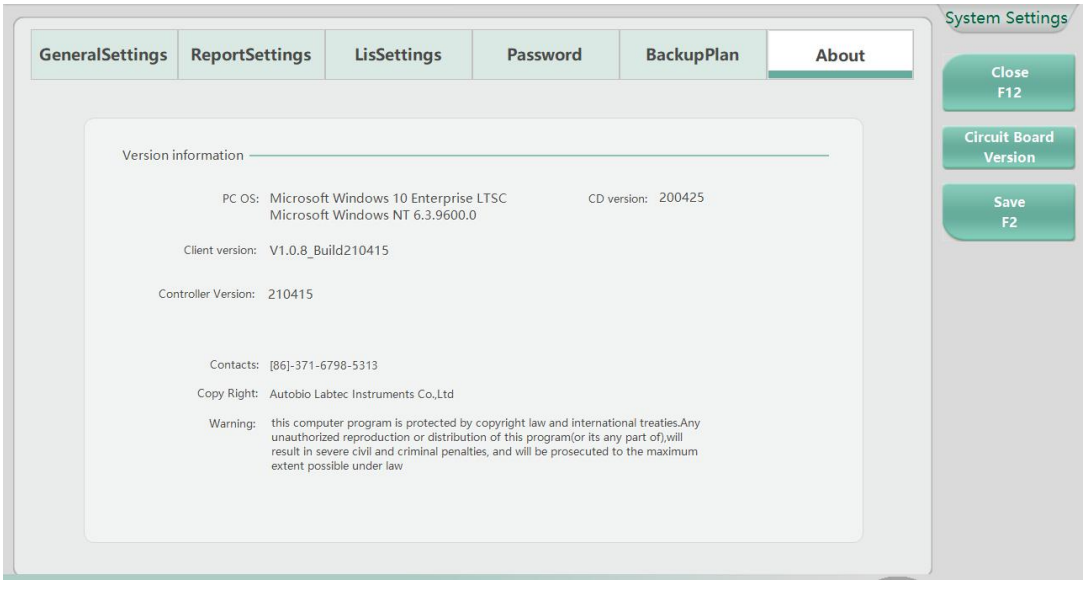
Version interface description:

Item	Description
Frequency	Set how often to back up, and cycle settings options include (daily, weekly).
Start Date	Set the date on which to start the backup, with the date settings options. (Monday, Tuesday, Wednesday, Thursday, Friday, Saturday, Sunday)
Next Backup Time	Display the date of the next backup.
Start Time	Set the time to start the backup. The time settings include (0-24).

1. After the settings are completed, click “Save F2” to take effect.
2. If it is anticipated to cancel, click [Close this window F12].

4.7.6 About

It is available for users to browse the system version information.



4.8 System Diagnosis

Click the “Diagnosis” button in the main interface of the system to enter the diagnosis interface, so that you can check the faults of the system. The following table is a description of the diagnostic items, please read it in detail.

Control button	Description
SRK Scanning	SRK scanning is performed to determine the bar code scanning function of the sample rack and the position of the sample cup to determine whether the sensor is normal. By starting to read the continuous bar code, the sample and reagent bar codes are continuously read.
Liquid Level Detection	By performing sample needle and reagent needle liquid level detection, it can judge whether the corresponding liquid level detection function is normal.
Quantitative Test	The difference between the measured value and the set value is compared by using the balance measurement, so as to judge the infusion precision.
Routine of PCR	Perform PCR tests, check the real-time temperature and PCR fluorescence value during the test to determine whether the PCR is normal. Verify the effect of automatic mixing. And the test data can be exported.

CAUTION

1.Please contact the technical service department of Autobio before the above diagnostic procedures, so as to ensure that the diagnosis and commissioning of the item can proceed smoothly.

2.Pay attention to precautions, warnings, prompts and explanations of the graphics, symbols and abbreviations used on the labels of medical devices involved, and other contents that should be marked.

3.Do not perform any operation or function not described in the manual. Failure to do so may result in incorrect test results, serious or fatal personal injury and material loss.

4.Although the device is equipped with a clot detection system, users cannot intentionally place a clot into a sample tube without Autobio's authorization. Any improper use associated with the default of the system is the sole responsibility of the user.

5.Improper use, adjustment, or non-compliance with procedures of some components may result in dangerous emission of laser radiation.

6.Only trained and authorized users can access the system. The system may encounter the risk of unauthorized access, resulting in possible data loss, damage or unauthorized distribution.

7.If the diagnostic system fails, please contact Autobio or a service provider.

5 Maintenance and Service

In order to ensure the accuracy of the experimental results, it is recommended to replace the following consumables regularly:
Parts list (including parts, accessories, consumables replacement period and method) is in the following table:

SN	Name
1	External Barcode Reader
2	Sample rack
3	Power cable
4	Internet work
5	Operating manual
6	RS232 cable
7	PCR consumables
8	Tip consumables

The following parts are suggested to be replaced regularly for the accurate test result.

No.	Name	Replacement Period	Replacement Method
1	Waste Liquid Tube	Every 12 months	To be maintained and replaced by Autobio customer service
2	Liquid Waste Tank Filter Film	Every 1 months	To be maintained and replaced by Autobio customer service
3	Peristaltic Pump	Replace pump head for every 45,000 tests	To be maintained and replaced by Autobio customer service
4	UV Lamp at Operating Area	Every 2 years	To be maintained and replaced by Autobio customer service
5	UV Lamp at Solid Waste Bin	Every 2 years	To be maintained and replaced by Autobio customer service
6	Ballast at Solid Waste Bin	Replace after use it for 3000 times	To be maintained and replaced by Autobio customer service
7	Laminar Flow	Every 6 months	To be maintained and

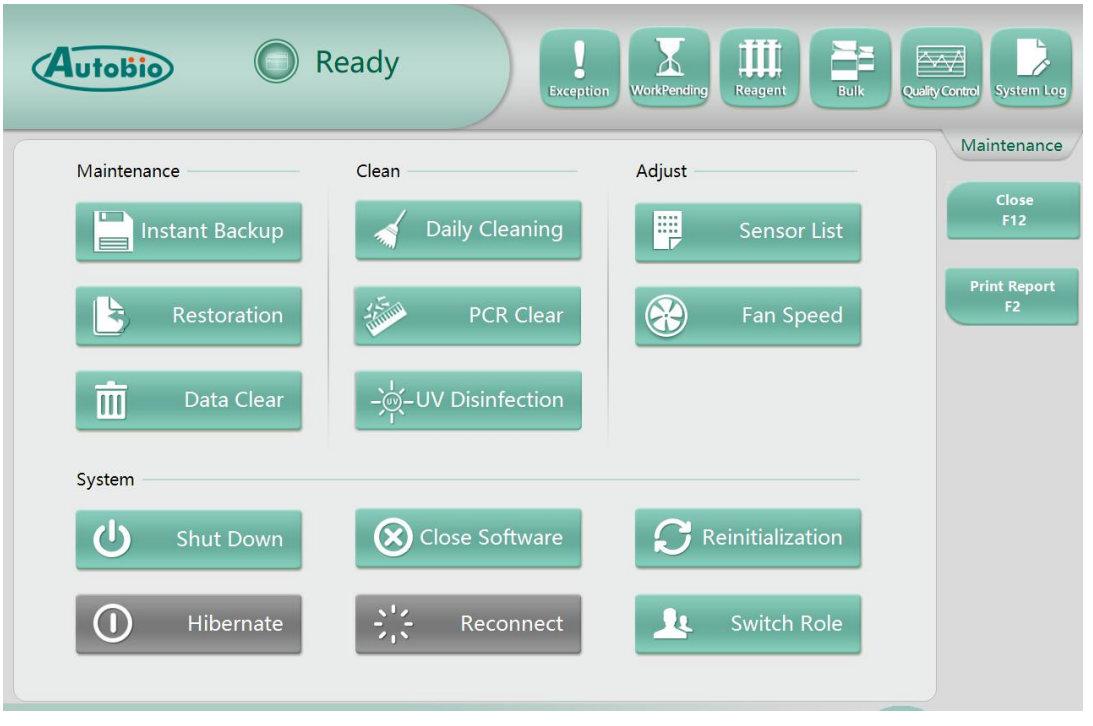
	Hood Screen		replaced by Autobio customer service
8	Channel Shrapnel	Every 2 years	To be maintained and replaced by Autobio customer service

Unauthorized or improper maintenance operations may result in serious personal injury and material damage.

In order to ensure the quality of the instrument, parts, accessories and consumer goods to be replaced shall only use the parts provided by Autobio.

The item of instrument maintenance is listed in the system maintenance menu. In order to ensure the normal operation of the instrument, please maintain the instrument and system according to the requirements of system maintenance. If the damage is caused by improper maintenance, the maintenance cost shall be borne by the user.

Click maintenance under the main interface to enter the following interface:



NOTE

Some menus may not be displayed because of system permissions. It needs to be displayed under the mode of operation for a particular administrator. If you need to make adjustments to these items, please contact our engineers to determine if you can maintain and adjust the items.

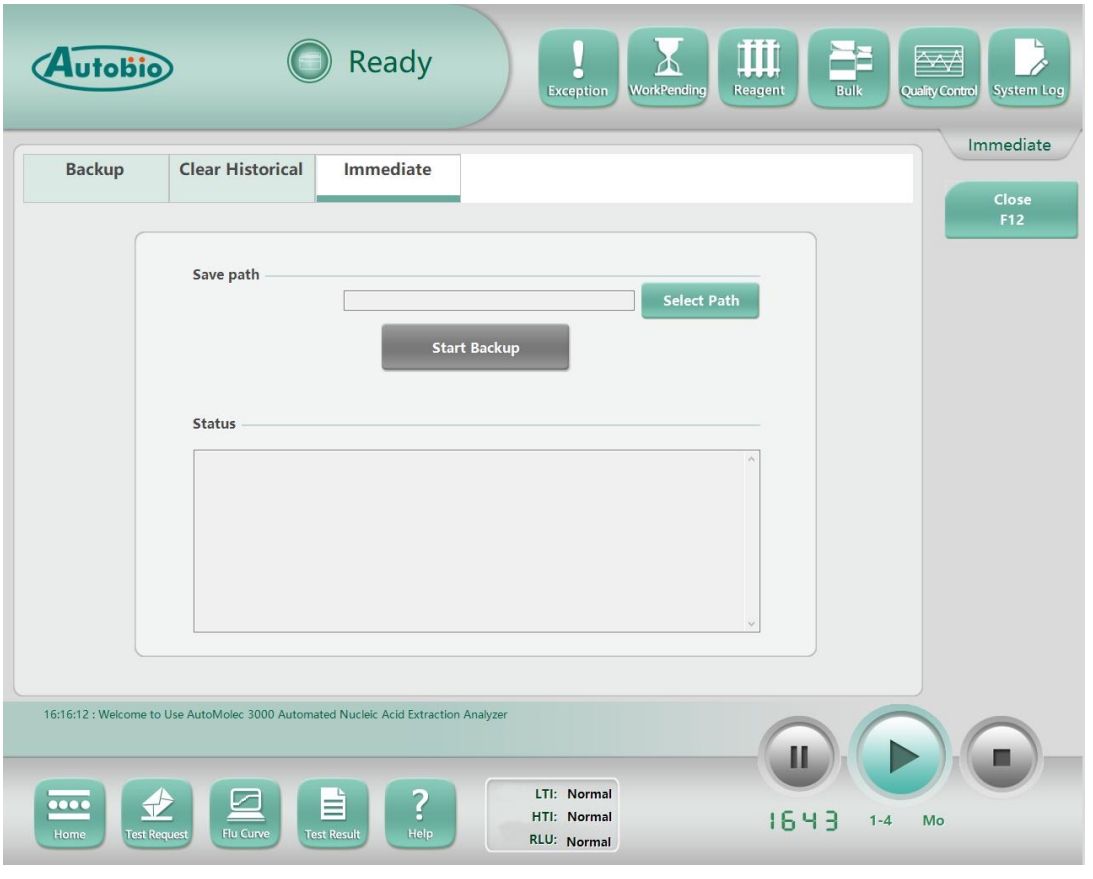
5.1 Maintenance

PROMPT: Maintenance operations require administrator privileges.

The maintenance menu includes instant backup, restoration, and clear historical data.

Backup information:

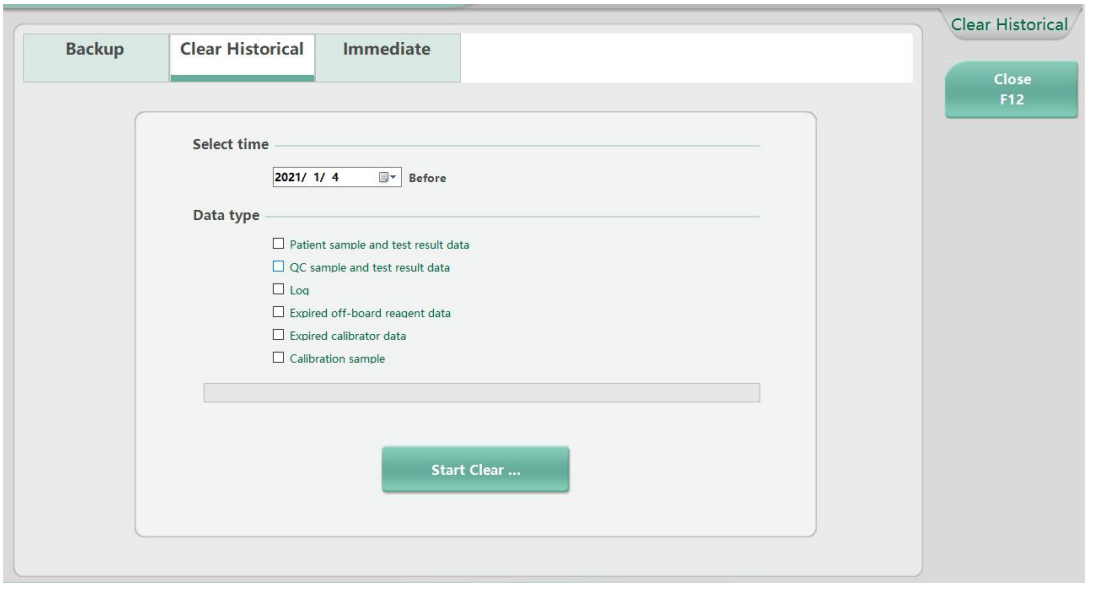
Backup the database to prevent data loss due to database corruption or misoperation, you can choose the location to backup (default path :D:\Bak).



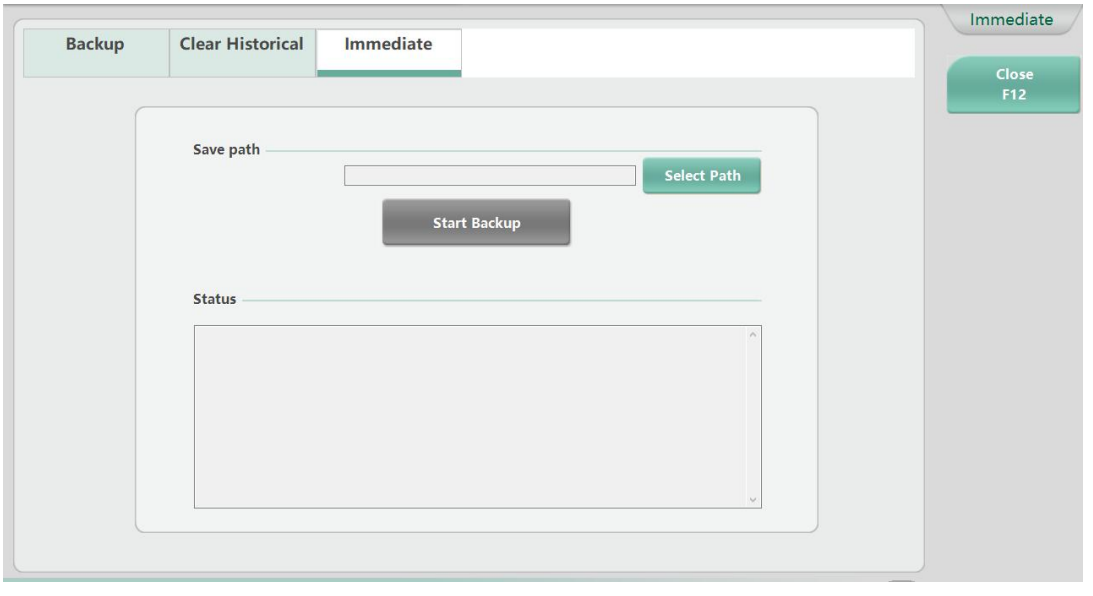
After the backup is completed, you can select [information] to view the backup details, which mainly include: backup status, backup time, and storage location.

Clearing of historical data:

You can also selectively delete records you don't need through time selection and data type selection under the clear history interface. This operation is not recoverable and it is recommended that you confirm the data to be deleted before proceeding.

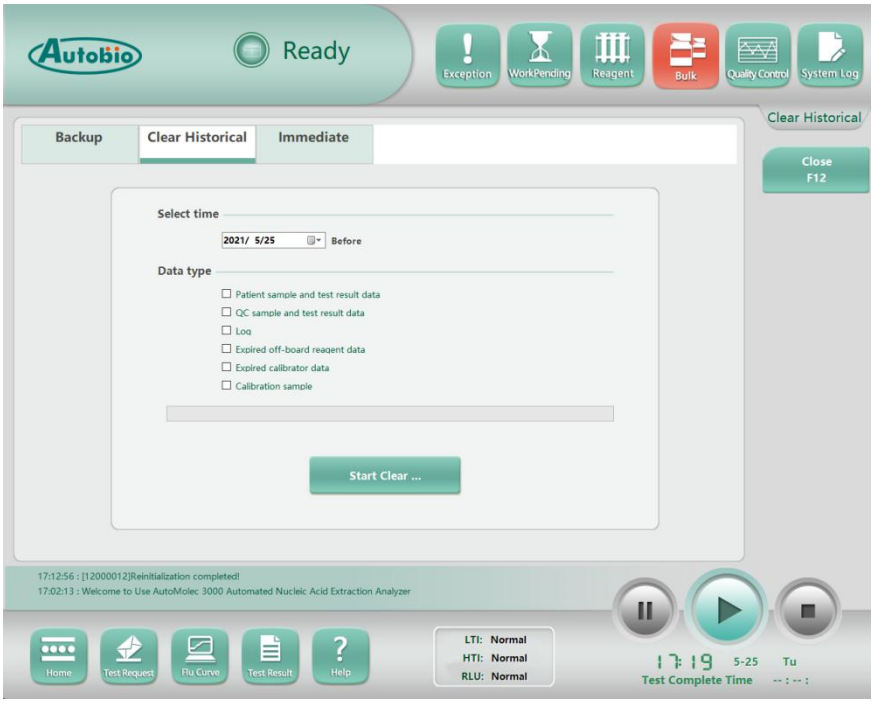


5.1.1 Instant backup



You can also backup the client database at any time by clicking “Start Backup” after selecting the backup path.

5.1.2 Clear Historical



Name	Description
Select time	Clear the data in the selected time
Patient sample and test result data	Clear the patient sample and test result data
QC sample and test result data	Clear the QC sample and test result data
Log	Clear the log
Expired off-board reagent data	Clear the expired off-board reagent data
Expired calibrator data	Clear the expired calibrator data
Calibration sample	Clear the calibration sample

Note: Please confirm whether to delete the historical data before clearing. Once the data is cleared, it will not be retrievable.

5.1.3 System Recovery

Select system recovery, and the screen will pop up a dialog asking whether to recover the entire system, and check yes or no. The recovery system will initialize the system, so the database should be backed up before system recovery to prevent database damage and data loss caused by incorrect contents of the recovery.

CAUTION

System recovery operation can only be carried out by the company's engineers or designated qualified personnel!

PCR unit maintenance:

In order to ensure the best performance of your AutoMolec 3000, it is recommended to check each reaction hole of the PCR unit once a month. If there are dust or impurities in the reaction hole, you can gently swab with a blown balloon. When the dust or impurities cannot be completely cleaned by the ballooning method, a cotton swab can be dipped in anhydrous ethanol to clean the reaction hole.

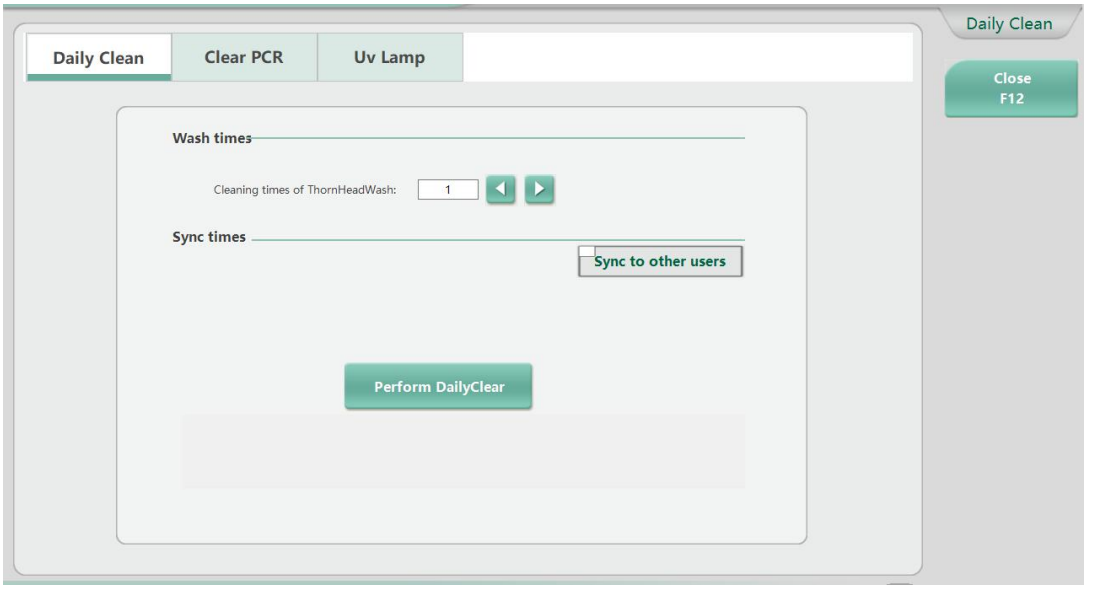
In addition, it is recommended to perform fluorescence calibration for the PCR unit every 6 months. Please contact a professional engineer to perform this maintenance.

5.2 Clean

5.2.1 Daily Clean

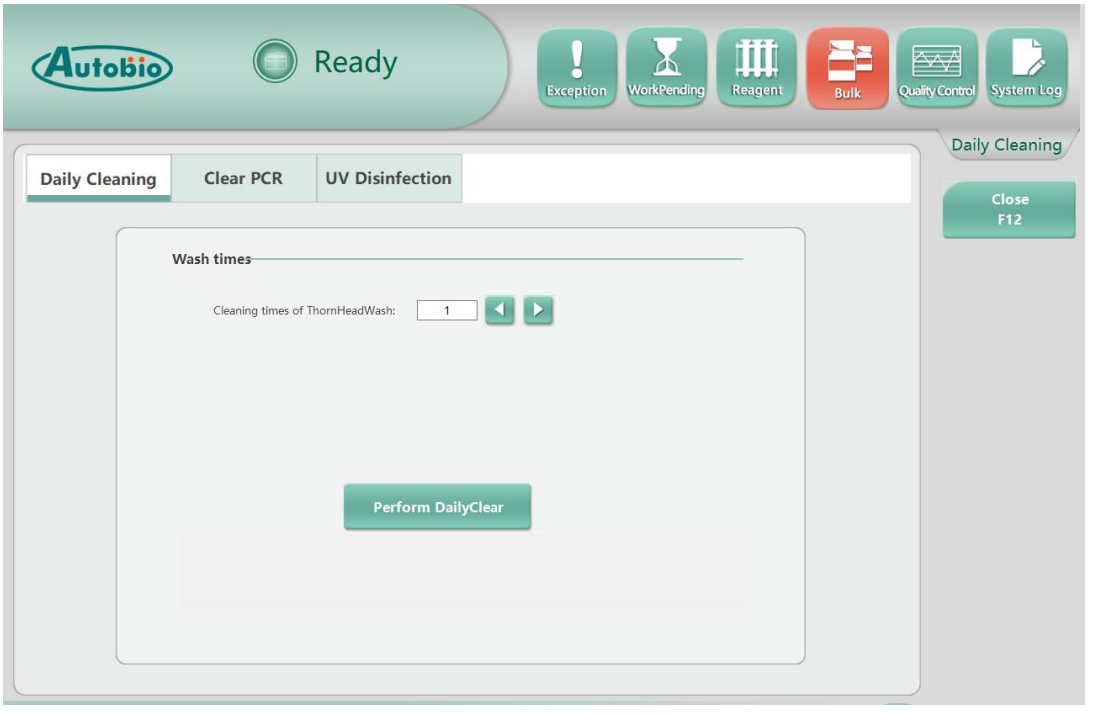
A cleaning procedure should be carried out before starting the experiment each day. It is recommended that the needle flushing times of waste liquid should not be less than 3 times.

Adjust the cleaning times by the left and right arrows or directly enter the cleaning times, click to perform daily clean and do not try to stop the process of the instrument during the cleaning process, so as to avoid database damage or operation failure.



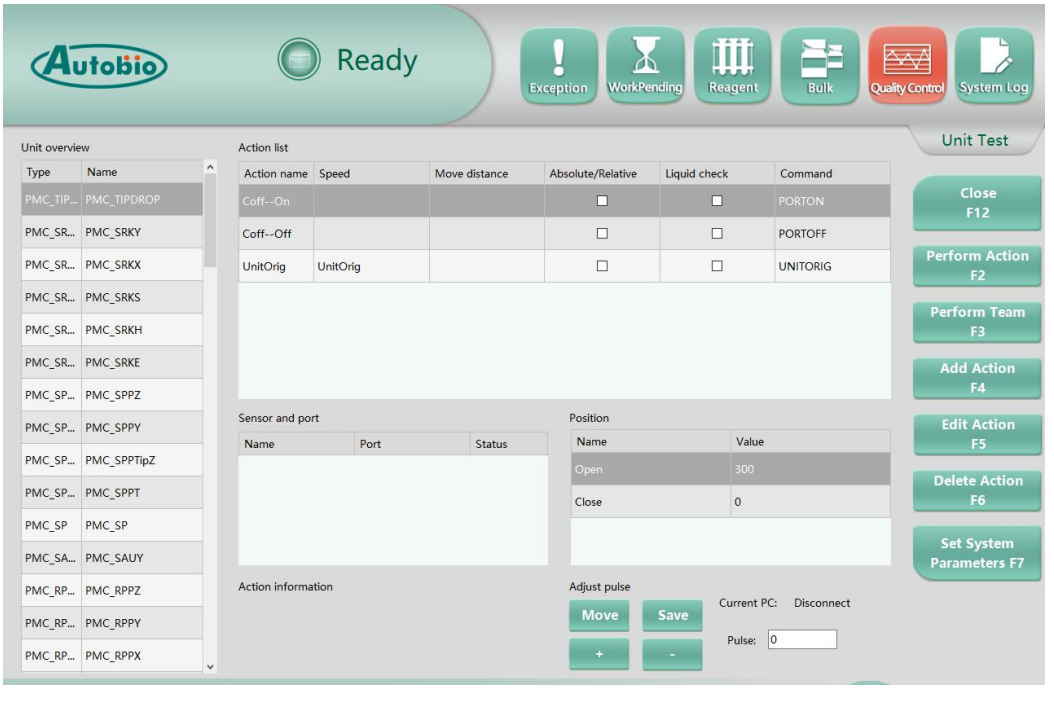
5.2.2 Clean PCR

It is recommended that you perform clean PCR operation before the experiment begins every day. Click the “Clean PCR” button, and the instrument will automatically perform clean PCR operation.



5.3 Debugging

5.3.1 Unit Test

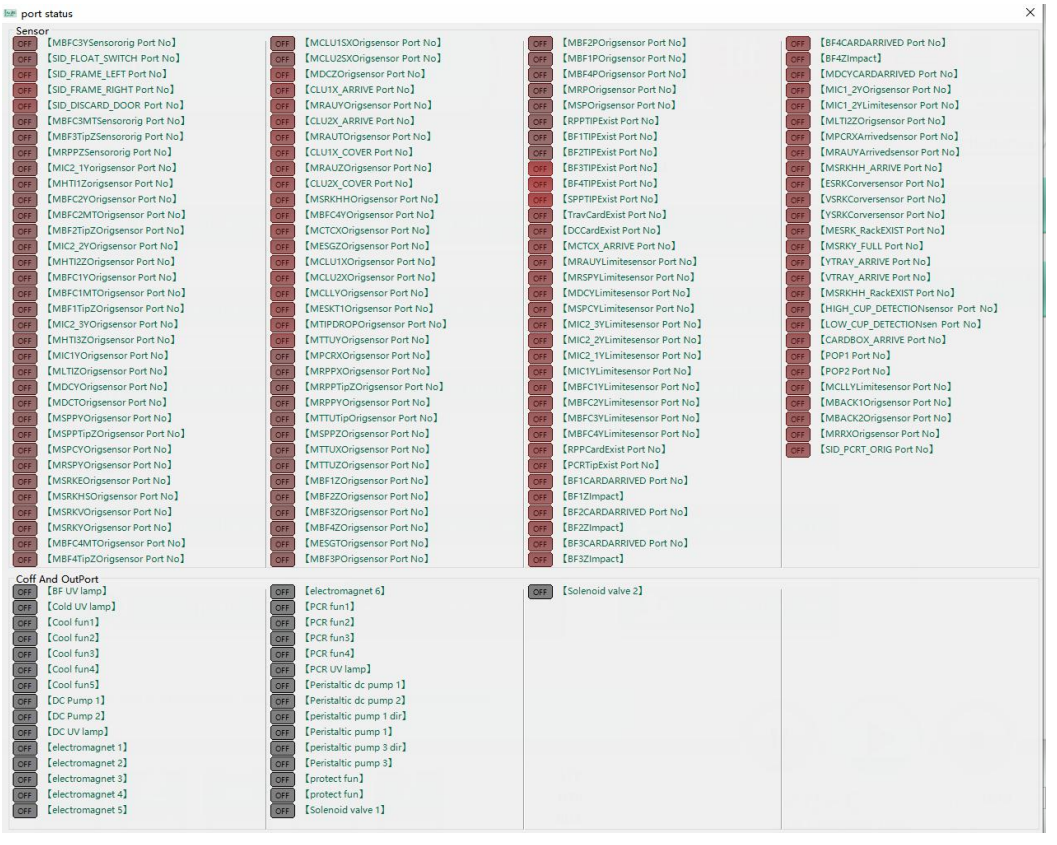


It will display parameters of each motor for maintenance of the instrument by the service engineer.

CAUTION

Unit test can only be executed by Autobio Engineer or qualified personnel authorized by Autobio.

5.3.2 Sensor Lists



The list shows the state of each sensor and port in the instrument, which is convenient for you to check the problems and give feedback.

5.4 System

5.4.1 Shutdown the system

Turn off software and computers if you intend to move the instrument or if you intend to shut down the system for an extended period of time (more than 5 days).

5.4.2 Close the software

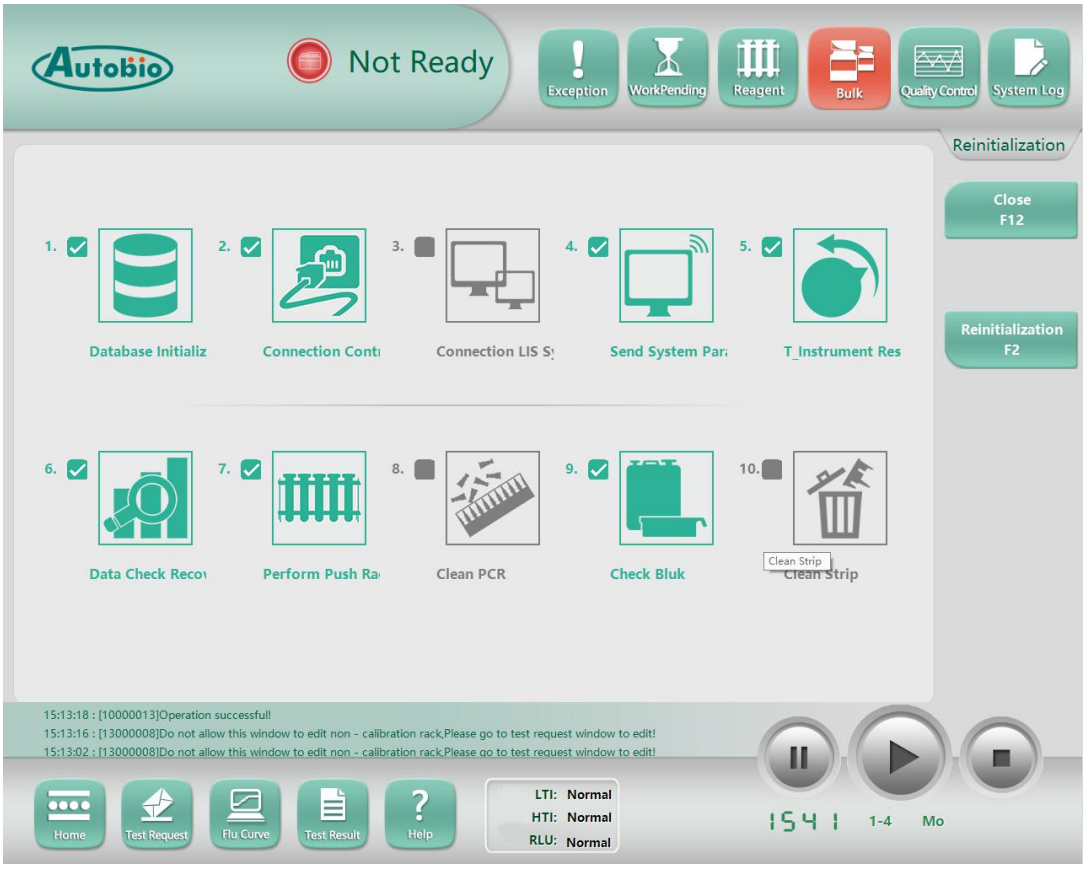
After using the client software, click the button to close the client software.

5.4.3 User switch

Switch users with different permissions.

5.4.4 Reinitialization

Reinitialization is the process of initializing the control system and operating system in an unready state. Select the item you want to initialize and perform the initialization. The system initializes the default item and you can manually change the item that needs to be initialized.



CAUTION

Perform the initialization function to check the communication status between the computer and the instrument, the mechanical position of the instrument, sensors, consumables, reagent information, *etc,*. Instrument operation should be performed only when all initialization is complete. Please wait patiently during initialization.

5.5 Transportation Requirement

The requirements of temperature and humidity should be fulfilled, that is to say, the instrument should be water-proof and damp-proof during transportation and handling, and free from serve vibration and force, squeezing. Handling, loading and unloading should be conducted under the guidance of professional engineers or in accordance with the

following methods. It is prohibited to transport the instrument without packaging. Before transportation, please check the integrity of the instrument packaging, anti-vibration and tilt indicators. At the same time, please check whether the direction of the "upward" sign of the instrument packaging is correct. After loading, please fix the outer packing of the instrument on the inner wall of the trunk with binding and tightening device. The instrument should be transported on a three-level or above highway. The speed of the three-stage highway is 30 km/h ~ 40 km/h; the speed of the second-stage highway is 40 km/h ~ 50 km/h; the speed of the first-stage highway is 60 km/h ~ 70 km/h; the speed of the expressways is not more than 80 km /h. When passing through the speed belt and uneven road surface, the speed should not exceed 15 km/h, and it should avoid sudden braking in the whole journey, and minimize vibration. Please check the packing and anti-vibration and tilt indicator status after transportation. The figure below shows the trouble-free state of the indicator and the normal direction marked upward.

Tilt indicator (no problem condition) *Vibration proof indicator (no problem state)* *upward*

5.6 Storage Requirement

The non-open or indoor storage that keeps the instrument with package at the temperature of -4 0℃ ~ 55 ℃ and with relevant humidity no more than 90 % should meet with the following conditions:

1) Be clean, tidy without accumulated water, grass, chemical medicine and corrosive gas;

2) Good ventilation without pollution source;

3) Safeguarding the instrument from direct sunlight and humidity.

The storage of unpacked instrument should also meet the temperature and humidity requirements above. Precautions of dust-proof and water-proof should be taken, such as heat shrinkable film and plastic bags. Besides, there should be enough clearance between the instruments and floor, wall, ceiling and radiator to prevent unnecessary damage. The distance between the instrument and the wall and ceiling shall be no less than 30 cm, the distance between the instrument and the radiator or heating pipe shall be no less than 30 cm, and the distance between the instrument and the ground shall be no less than 10 cm.

The instrument shall be cleaned and emptied for a long time storage, and the relevant peripheral accessories shall be well preserved and packaged as a whole, registered and sealed. If the instrument is kept for more than three months, please contact with after-sales engineers to evaluate the instrument before reuse.

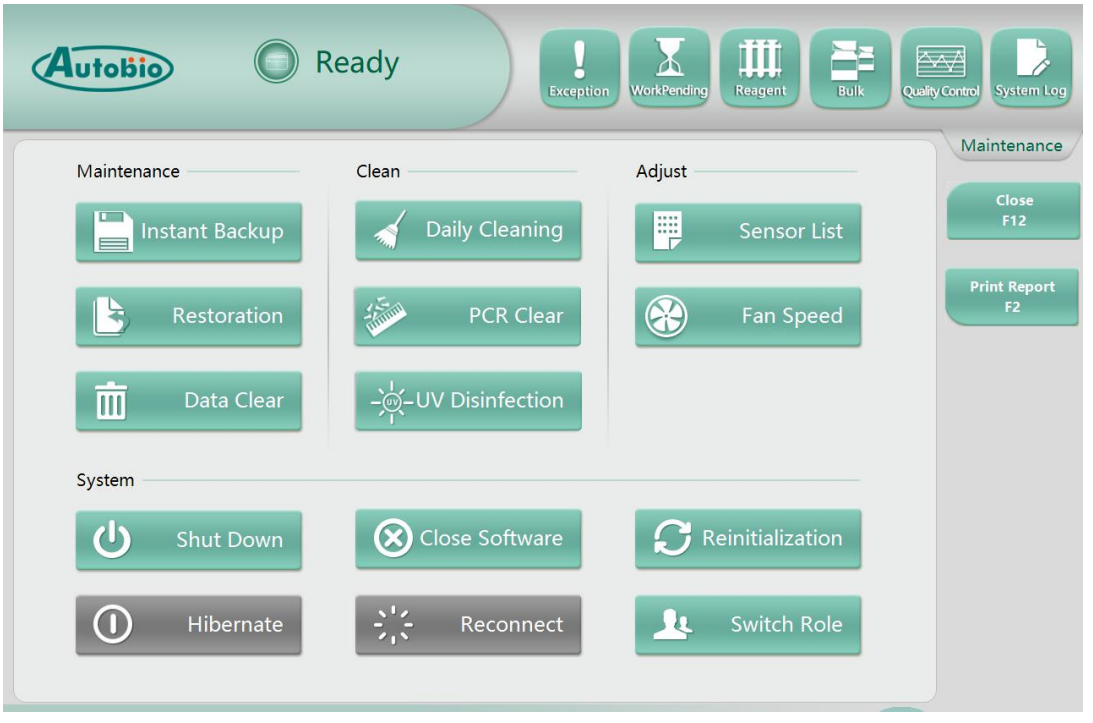
Unauthorized or improper maintenance operations may result in serious personal injury and material damage.

6 Test Operation

6.1 Reinitialization

After the client software is started, perform reinitialization:

1. Click the maintenance on the main interface of the client-side to enter the maintenance interface.



2. Click the “Reinitialization” button on the “Maintenance” interface to enter the reinitialization interface.

3. If tests need to be obtained from LIS check “Link to LIS System” when reinitialization.

4. Select the clean PCR unit on the reinitialization interface.

5. Check whether there is a strip in the extraction channel. If there is a strip, check to clear the strip.

6. Click the “Reinitialize” button on the right.
7. After the reinitialization is completed, the states of module A and B are in the “Ready” state.

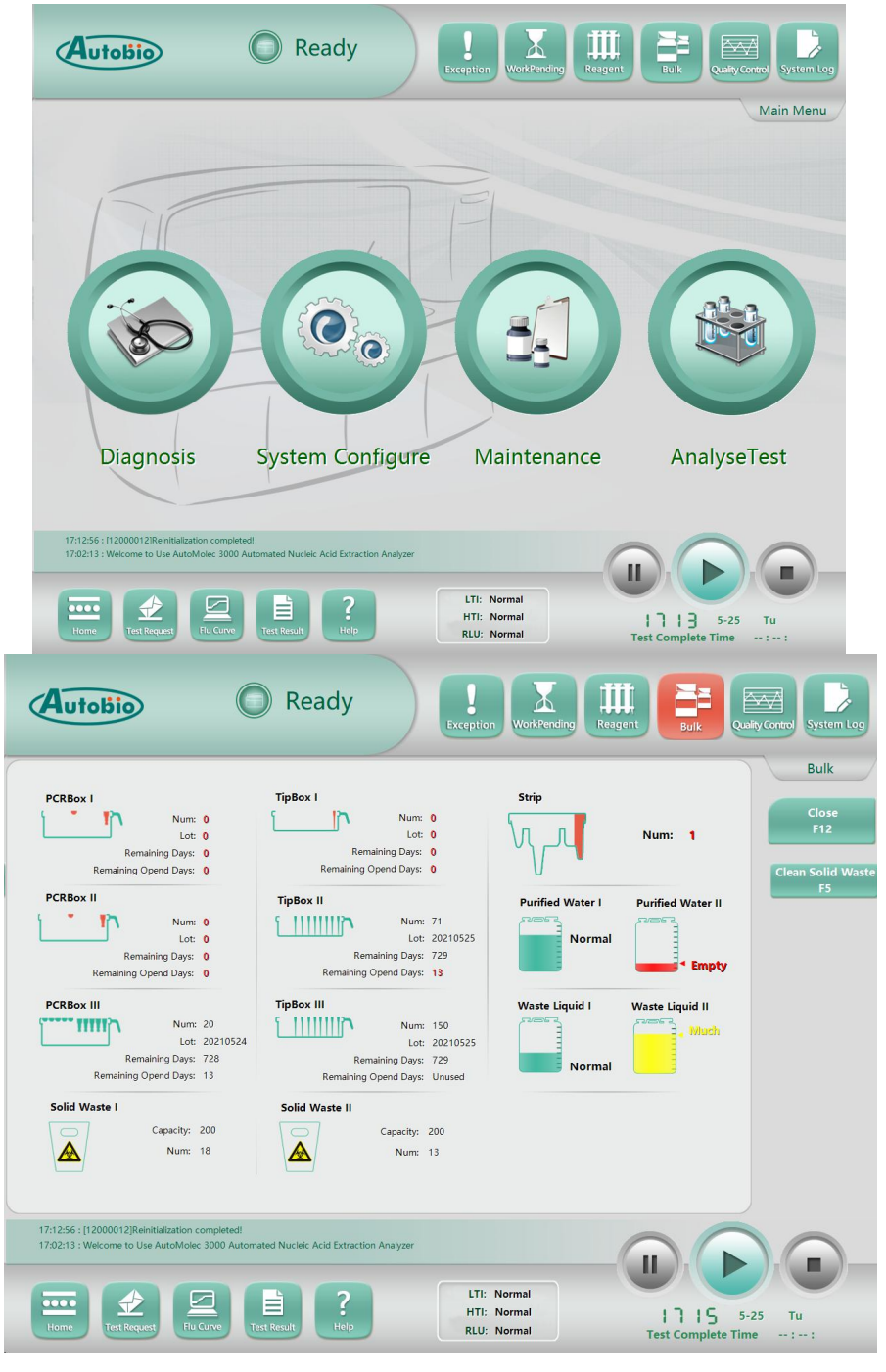
6.2 Reagent Inspection

1. Click the “Reagent" button above the software to enter the “Reagent Information" window.

2.Check whether the remaining usage times of kits for each item on the instrument are sufficient. If not, please add reagents in time.(See Section 9.1 Reagent information for operations).

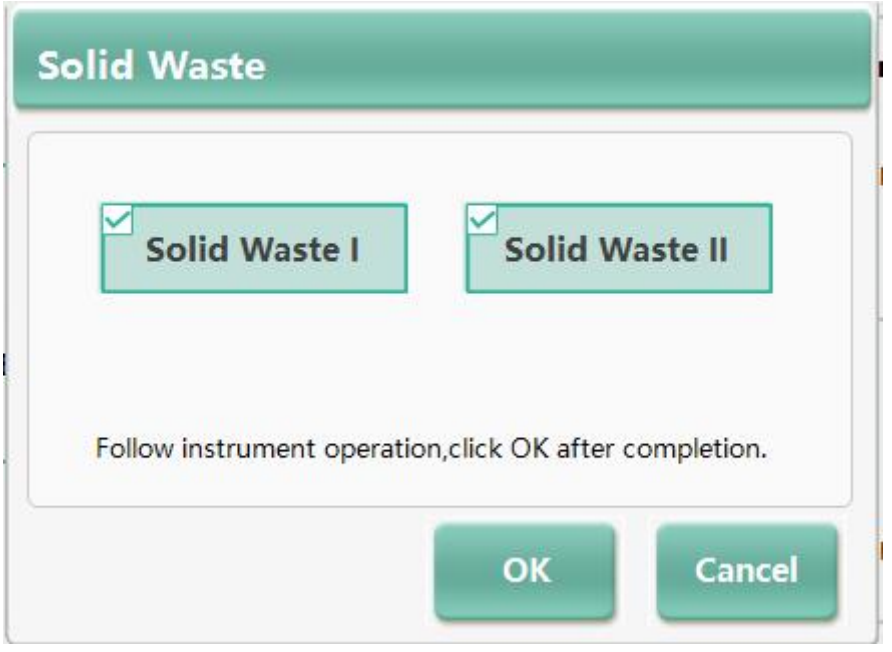
6.3 Consumables Inspection

Click the “Consumables” button above the software to enter the consumables interface.



6.3.1 Clean Solid Waste

1. Select "Clean Solid Waste" button to switch to the dialog box of solid waste.



2. There are two solid waste bins, you can select the one required for cleaning.
3. Open the waste bin hatch;
4. Pull out of the waste bin and take off the biological waste bag;
5. After cleaning, put on the waste bag and send the waste bin to the original place and close the hatch;
6. Click “OK” button.

WARNING

During the cleaning process, you may come into contact with potentially infectious substances, and please handle and dispose these biologically hazardous materials in accordance with proper laboratory procedures. Take necessary protective measures to protect your hands and eyes.

6.3.2 Replace PCR Tube

During the test run, check the consumables interface and find that the remaining number of PCR tubes is insufficient:

1. If there is an empty slot in the consumables area of the PCR tube, insert the PCR tube consumables box that needs to be added directly into the empty slot. After insertion, the instrument reads the RFID information on the PCR tube consumables box and can display the information of the newly inserted PCR tube consumables on the consumables interface.
2. If there is no empty slot in the consumables area of the PCR tube, take out the PCR tube which is not used and insert the new PCR tube consumables box. After insertion, the instrument reads the RFID information on the PCR tube consumables box and can display the information of the newly inserted PCR tube consumables on the consumables interface.

6.3.3 Replace Tips

During test run, if the left test of the tips is not enough,

1. If there is an empty slot in the tip consumables area, insert the tip consumables box that needs to be added directly into the empty slot. After insertion, the instrument reads the RFID information on the tip consumables box and can display the information of the newly inserted tip consumables on the consumables interface.
2. If there is no empty slot in the tip consumables area, take out the tip consumables box which is not used and insert the new tip consumables box. After insertion, the instrument reads the RFID information on the tip consumables box and can display the information of the newly inserted tip consumables on the consumables interface.

6.3.4 Replenishment of Purified Water

During the test run, the client interface prompts the message “Purified water is insufficient, please complete the replenishment within 20 minutes” or finds an alarm of purified water shortage in the consumable interface.

Open the door of placement area where purified water is placed and unplug the quick insertion device on the purification container with less purification water, take out the purified water container the it will automatically switch to another purification container, place the previous container to the placement area after adding the purified water in it. Plug the quick insertion device then close the hatch and the replenishment is completed.

CAUTION

When perform the replenishment of the purified water, do not take out of the two containers at the same time, otherwise, the instrument will stop adding the sample for testing.

6.3.5 Handling of the Waste Liquid

During the test run, the client sends a message of “Waste liquid container is nearly full, please clear it off within 20 minutes” or fan alarm of too much waste liquid in the waste liquid container displays on the consumables interface;

Open the door of placement area where waste liquid container is placed and unplug the quick insertion device on the waste liquid container with more waste liquid, take out the waste liquid container then it will automatically switch to another waste liquid container, place the previous container to the placement area after dropping off the waste liquid. Plug the quick insertion device then close the hatch and the handle of the waste liquid is completed.

6.3.6 Replenishment of Strips

During the test run, if strips warning displays in the log at the upper right corner or consumables interface, open the cover of strip bin 1 or strip bin 2 to replenish the strips. Close the cover after replenishing the strips. The number of strips is calculated by the push

hand movement of the strips management unit. The consumables interface will display the number of strips of storage bin.

WARNING

During the cleaning process, you may come into contact with potentially infectious substances, and please handle and dispose these biologically hazardous materials in accordance with proper laboratory procedures. Take necessary protective measures to protect your hands and eyes.

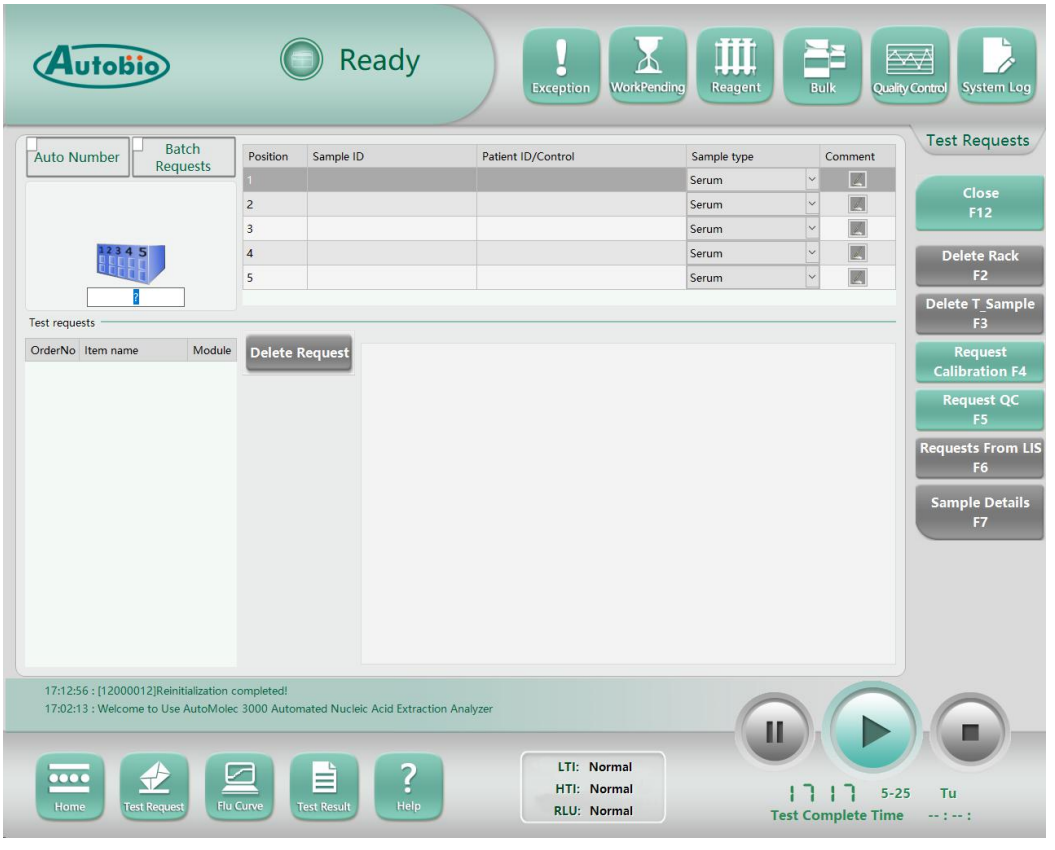
6.4 Test

6.4.1 Samples Pretreatment

Handle the sample before test according to requirements.

6.4.2 Patient Samples

Run the software into the main menu interface, and select “Test Analysis” to enter the interface of the test and analysis wizard interface, and select “Test Requests” to enter the patient test request interface to manage the patient test samples.



Interface description:

Item	Description
Sample Rack No.	Click "? "with the mouse to activate the sample rack input box.
Location	Fixed autonumber, from 1 to 5.
Sample No.	Sample barcode or number
Case No./Quality Control	The case number name of the sample or the name of the quality control.
SampleType	Sample types include: serum, plasma and urine sample types.
Note	Notes for the sample.
Automatic Numbering	Enable this function, and the number of the next sample can be automatically generated when the patient test sample is input (No manual input is required for sequential increments).
Batch Request	Enable this function, and the last sample's detection request is copied to generate a new detection sample. The main purpose of this function is to facilitate the input of a large number of samples for testing the same items.
Close	Exit the interface and return to the corresponding second-level navigation (detection, analysis, maintenance, diagnosis) interface; If you do not enter any secondary navigation interface before entering this interface, you will directly return to the main interface.
Delete Sample Rack	Delete the current rack and the sample information it contains. If the rack number does not exist, the button is not available.
Delete Information about the Sample	Delete the currently selected sample and the detection request information it contains. If the sample does not exist, the button is not available.
Calibration Request	Switch to the calibration test sample management interface.
Quality Request	Add quality control test samples.
Request for a LIS	Get online information button, and the button is not available if the sample does not exist or if the sample is not a patient sample.
Sample Information	Display the currently selected sample information. If the sample does not exist, the button is not available.

NOTE:

Each sample rack contains a maximum of 5 samples. After entering the patient's sample test request interface, the sample rack and its sample information are all empty. Only by

re-entering and selecting the sample rack no. can the sample information be displayed. If the sample rack no. already exists, the sample information it contains will be displayed on the interface accordingly. If the input sample rack no. does not exist, it will be added as a new sample rack and the sample information will also need to be added again.

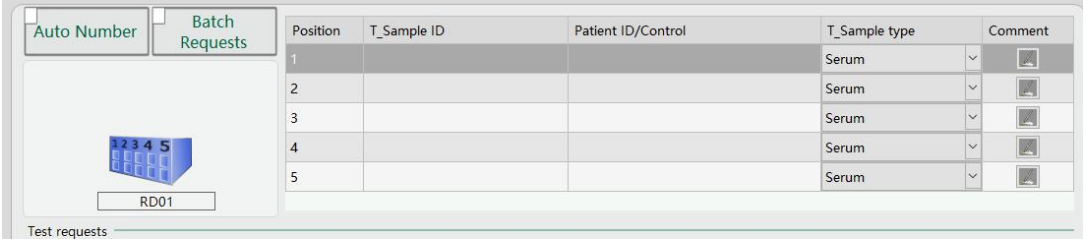
WARNING

In these processes, you will come into contact with potentially infectious materials. Handle and dispose these biologically hazardous materials in accordance with proper laboratory procedures. The hand, eyes and face must be properly protected.

6.4.3 Add a sample rack and sample

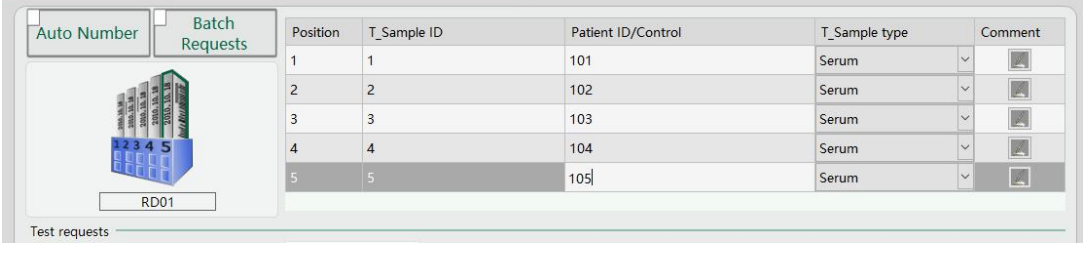
1. Click "? "on the interface to activate the sample rack input box.

2. After entering the sample rack number AK01 in the input box, you can enter the sample no. in the sample information bar, or scan the bar code by the scanner as the sample rack number.



1. After the sample number is input, the case number/quality control name, sample type and other information can be input. Here, the case number/quality control name can be entered first.

2. Set the sample type: serum, plasma, others (treated whole blood, urine, sputum, secretion swab and cervical exfoliated cell).



1. Add comments. Click the note button, and the edit note information box pops up. Enter the note in the information box. Click OK to add a note to the sample. At this point, the sample rack and its sample information input are completed.

2. Add the corresponding sample to the corresponding position of the instrument sample rack, then, the addition of the sample rack and its samples is completed.

CAUTION

1. Before the test begins, the sample rack and its sample information can be input first, or the sample can be added to the instrument sample rack before the information is input, and the test result will not be affected; If samples are added during the testing process, the sample rack and its sample information must be input first, and then the sample is added to the instrument sample rack, otherwise the system will not be able to recognize the newly added sample after the testing begins, and the sample rack will be directly pushed out and cannot be tested.

2. The input bar code of the sample rack shall be consistent with the actual bar code of the sample rack.

3. In order to ensure the reliability of test results, please check the sample residual quantity before starting the experiment. The left quantity of sample should be no less than 150 uL(dead volume) plus the required quantity of actual test.

Dead Volume: The dead volume is the quantity of liquid left in the sample tube/cup that cannot be pipetted by the needle due to mechanical limitations and calculations.

NOTE

1. The sample rack number is composed of an identification code and an ordinal number, which can be two or four digits. When it is two, it must be a number and the input range is 01-99; When it is four, the first two characters must be upper case and the last two characters must be numerical and the input range is from 01 to 99. The barcode generation format is code128, and the instrument cannot recognize the barcode generated in other formats.

2. Before entering the sample information (including the case number, sample type, and notes, *etc,.*), the sample number must be entered first, otherwise the sample information cannot be input; Sample information should be selected and filled in according to users' needs.

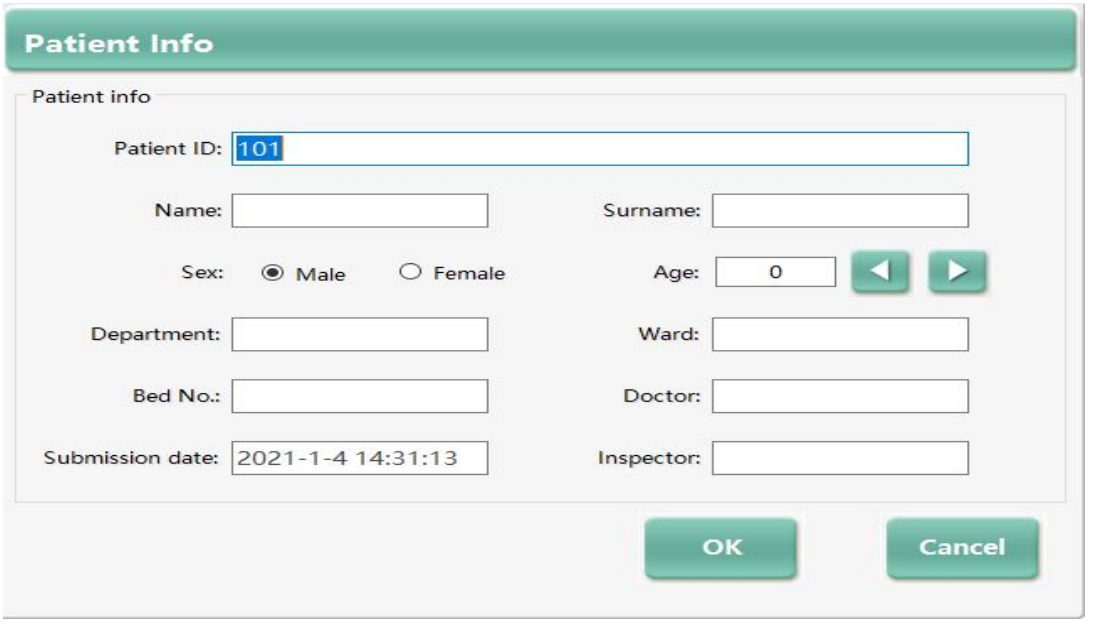
3. The sample number and case number can only be letters (A~z) or numbers (0~9).

6.4.4 Edit Patient Information

After adding the sample rack and its sample information, the following methods can be used to edit the patient information:

1. Select the sample of patient information to be edited and click the sample information button to pop up the patient information box.

2. Edit all information of patients.



3. Click OK, and the new edit information will be saved.

Click the sample information button again, and the patient information that pops up is the information saved after editing.

6.4.5 Input Test Request

Select a test request for the current sample. You can select one or more tests for each sample.

1. Select the sample that needs to be added to test request.

2. Add requests to standard tests that need to be detected.

6.4.6 Delete Sample Racks and Samples

1. Delete the sample

1) Input sample rack number to be deleted in the input box of sample rack number.

2) Select the sample to be deleted.

3) Click the “Delete Sample” button on the right side of the interface.

d) After selecting “OK”, the sample and the detection request information contained therein will be deleted, and the corresponding sample will be removed from the sample rack.

2. Delete the sample rack

1) Input the sample rack number to be deleted.

2) Click the “Delete Sample Rack” button on the right side of the interface.

3) Click “OK” and the sample rack and the sample information will be deleted.

4) Remove the corresponding sample rack from the instrument if necessary.

CAUTION

If the sample goes into the sampling line, the software will not be able to edit it, and it is impossible to move it or take it out.

6.4.7 Request for LIS

1. Add a sample rack.

2. Select the position of the sample on the sample rack.

3. Input sample number.

4. Select the "Request for LIS" button.

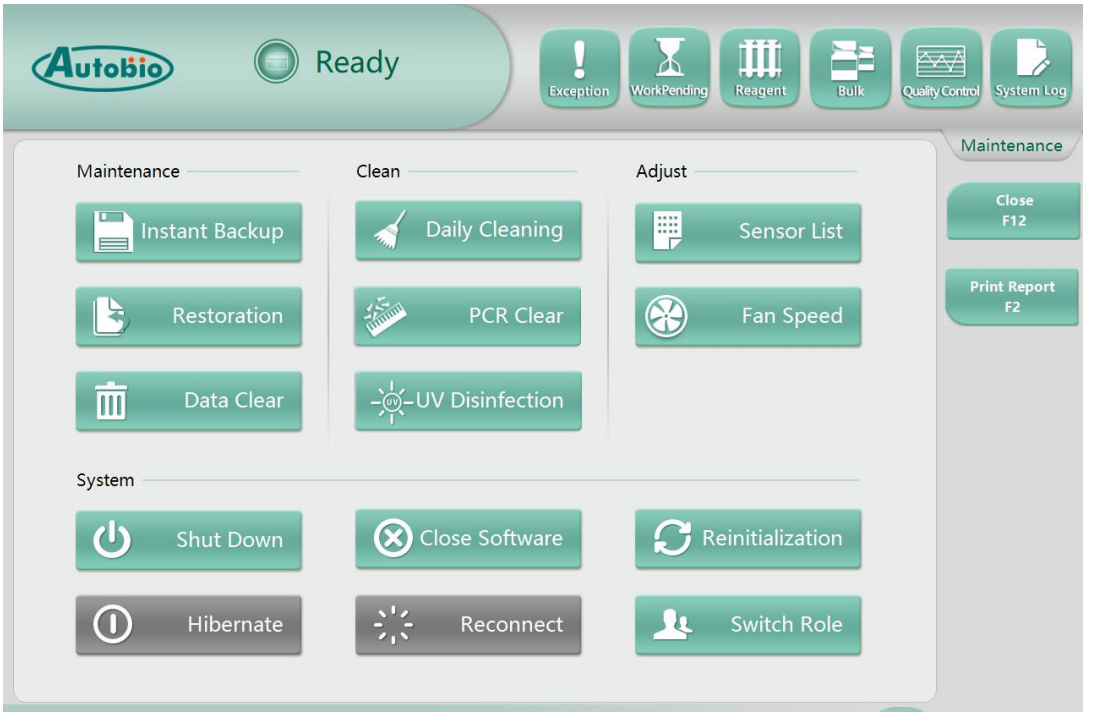
5. After clicking "Yes", the sample rack and the sample information it contains will be covered.

6.4.8 Start the Test

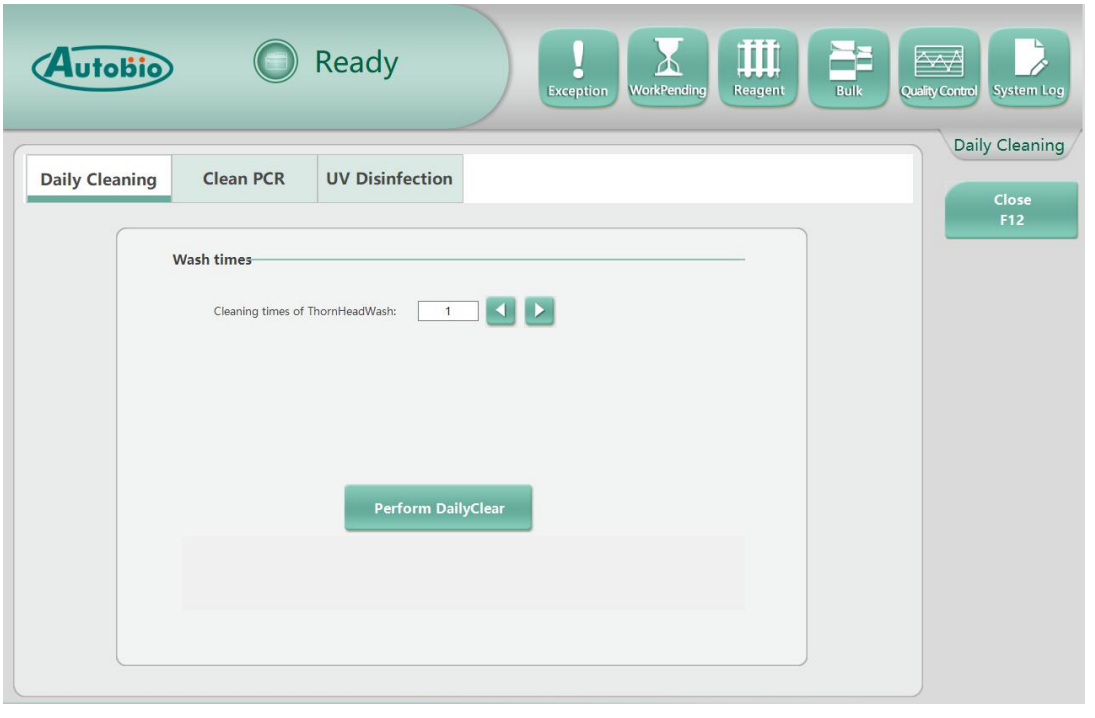
After sample editing is completed, put the sample rack into the sample rack loading device correctly, cover the sample rack loading device (SRK), and click the “Start” button at the lower right of the software to start the test.

6.5 Daily Clean

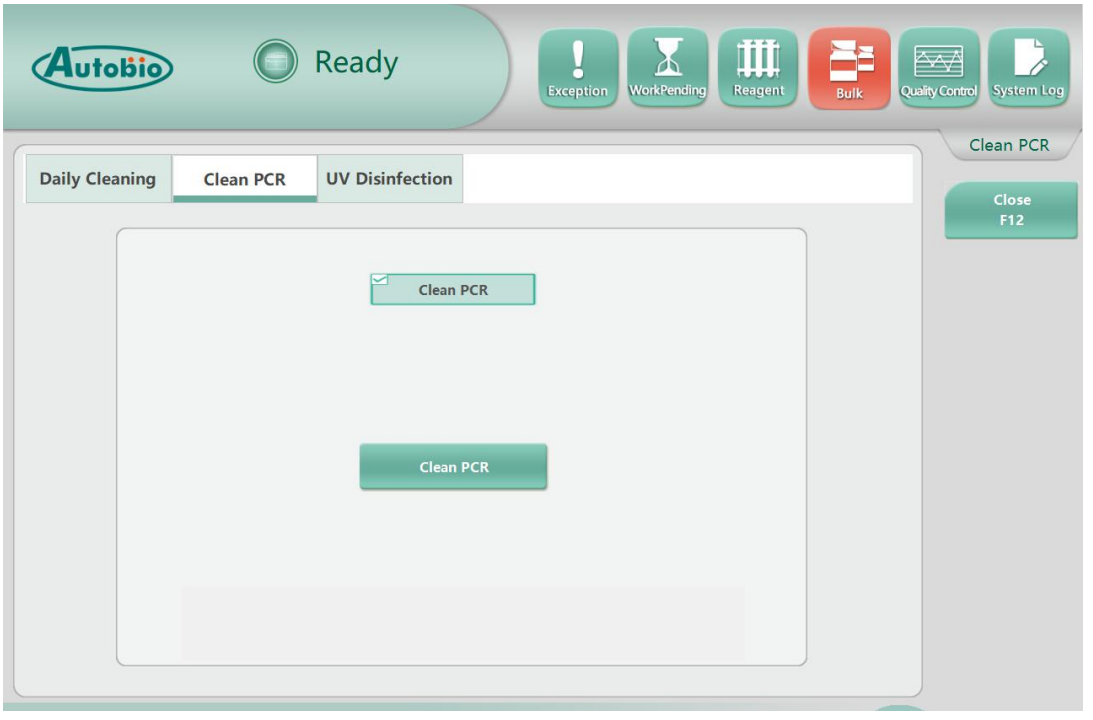
On the main interface of the software, click "Maintenance" -- "Daily cleaning" to enter the daily clean interface.



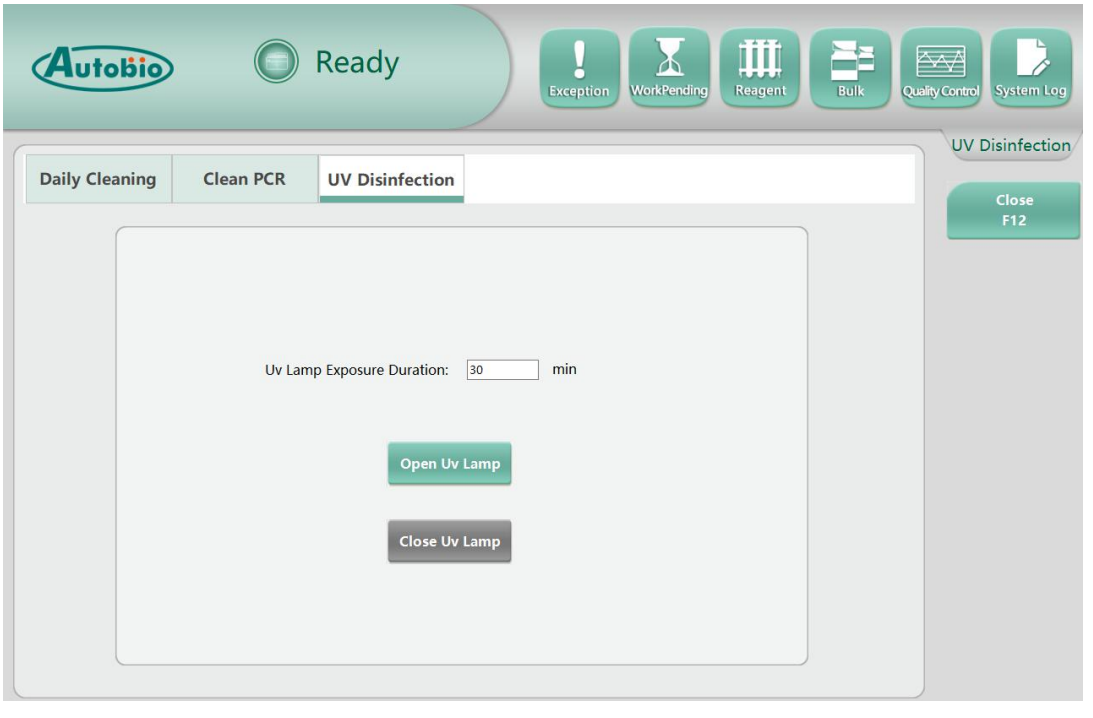
6.5.1 Daily Clean



6.5.2 Clean PCR



6.5.3 Ultraviolet Lamp Disinfection



6.5.4 Instrument Interior Clean

1. Turn off the power switch at the back and bottom right of the instrument.

2. Open the main cover.

Use hypochlorous acid disinfectant solution (secondary cleaning with purified water must be carried out within 30 minutes) to wipe the Sample inlet unit, RLU and ESK

3. After cleaning, close the left and right cover of the instrument to make sure that the interlocking device is normal.

CAUTION

1. Hypochlorous acid disinfectant can irritate the eyes and skin. Proper laboratory procedures should be followed.
2. Electric shock may occur during the wiping process. Please make sure that the instrument is powered off before operation.
3. Do not use decontamination or cleaning agents which could cause a HAZARD as a result of a reaction with parts of the equipment or with material contained in AutoMolec 3000.
4. Please consult the manufacturer or its agent if there is any doubt about the compatibility of decontamination or cleaning agents with parts of the equipment or with material contained in AutoMolec 3000.

6.5.5 Instrument Exterior Clean

1. Turn off the power switch of the instrument.
2. Use a dry soft cloth dipped in hypochlorous acid disinfectant (be sure to clean with purified water within 30 minutes) to wipe the instrument cover.

WARNING

During the cleaning process, you will come into contact with potentially infectious substances, and please handle and dispose these biologically hazardous materials in accordance with proper laboratory procedures. Take necessary protective measures to protect your hands and eyes.

CAUTION

To ensure the accuracy of the test results, it is recommended that the liquid line be replaced once a year.
If cleaning and maintenance are not carried out as required or pipelines are replaced regularly, the experimental results may be inaccurate.

6.6 Shut Down the Instrument

At the end of the experiment and after the daily maintenance, please turn off the instrument (the instrument power switch is located behind the instrument on the left) and turn off the computer.

7 Troubleshooting

The following solutions are for simple errors. Please contact service engineer or technical personnel authorized by Autobio if there are any other problems or errors not indicated in the following table.

Description	Reasons	Recovery Solutions
No extraction strip detected	The extraction strip is not in place.	Reopen the upper cover of the instrument and place the tray in place.
	The sensor did not detect the extraction strip.	Perform again after reinitialization. If this fault still exists, contact the local engineer.
	The push hand sensor did not detect the extraction strip.	Contact a local engineer for maintenance.
Sample deficient test	1. The sample volume is deficient.	Continue testing after manually adding the sample.
	2. The reagent volume is deficient.	Continue testing after manually adding the reagent.
	3. Sampling position is offset.	Contact a local engineer for maintenance.
Alarm of tank liquid level	1. Waste liquid in the waste liquid container is excessive.	Timely clean up the waste liquid in the waste liquid container.
	2. Waste in solid waste bin is excessive.	Clean up the solid waste in time.
	3. Purified water in the purified water container is insufficient	After adding the purified water, continue testing.
Unable to start the test	1. The instrument is not ready.	Reinitialize the instrument.
	2. Reset of moving parts fails.	Click to perform the initial operation, and the instrument will perform the initial action. If it has not still been reset, contact the local engineer for maintenance.
Unable to start the test	The cover of the instrument is not closed.	Close the cover and click “Start” to run the test.

	The sample rack is not in place.	Place the sample rack in the specified location, click “Start”, and run the test.
	It is unable to connect to instrument.	Restart the instrument, click “connect”, and run the test. If the test is still unavailable, contact your local engineer for repair.
Failure to run client software	1. Click the software icon and there is no response.	Restart the computer and click the icon to run the client after the restart. If the fault still exists, please contact your local engineer for maintenance.
	2. There is a lag when operating the client software.	Restart the computer. After the restart, click the icon to rerun the client software.
	3. Client software collapses and exits.	Restart the computer. After the restart, click the icon to rerun the client software. If the fault still exists, please contact your local engineer for maintenance.

NOTE:

When the instrument is stopped for maintenance or treatment, the instrument shall be in a state of power off, and shall not be powered on until the engineer has confirmed the completion of maintenance; If you need to transport the instrument, you should wear protective gloves first and disinfect the instrument strictly in accordance with the “Cleaning” method in the “Maintenance and Service" in manual.

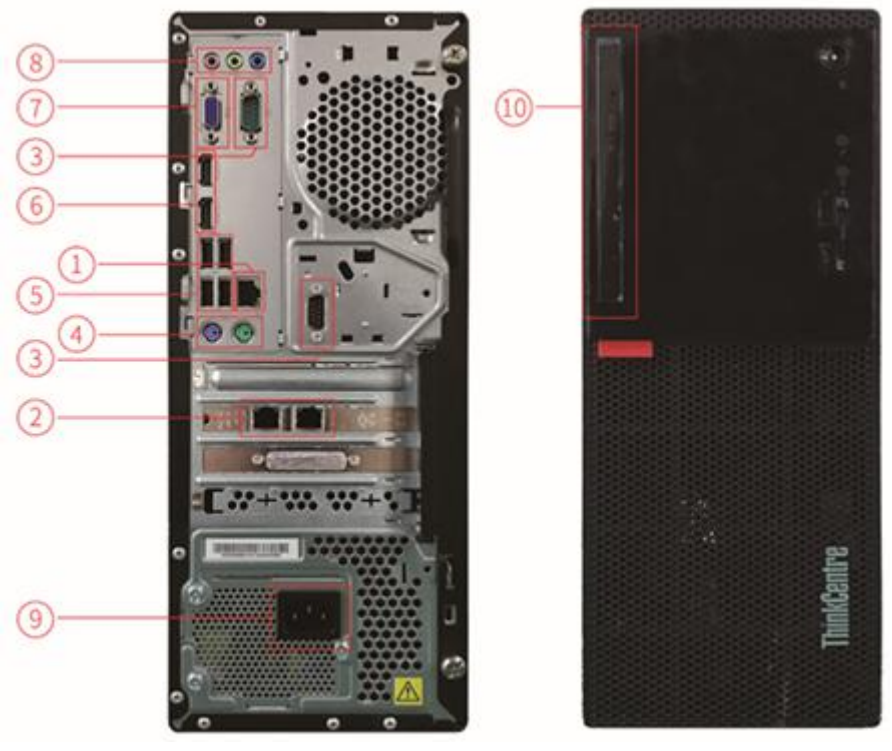
8 Relevant Description of Cybersecurity

Relevant description of cybersecurity is as follows:

8.1 Operating Environment

8.1.1 Hardware Configuration

Name	Configuration (Minimum Configuration)
Computer	i3 or above with main frequency of 2.5 GHz or above/memory of 8 G or hard disk of 500 G or above / 1280×1024 resolution or above
Firewall	Windows firewall



① RJ45 internet interface : It is defaulted that the instrument can be connected and set。

② RJ45 internet interface : It is used for external information exchange in network mode and is set according to the requirements of the user's network (such as local area network) . It is used for maintenance and updating.

③ Serial port: External information exchange port in serial mode is set according to the

requirements of user information network. The default baud rate is 9600.

④ RS/2 口：The connection supports RS/2 interface mouse and keyboard.

⑤ USB 口：External barcode reader, using HID protocol; connecting with keyboard, mouse, removable storage device, reading and writing standard format data for maintaining and updating of the company product. It is prohibited to charge.

⑥ HDMI interface：Connecting LCD.

⑦ VGA interface：Connecting LCD.

⑧ Audio mouth: Input/output audio signal.

⑨ Power interface: Connecting power supply.

⑩ CD drive: Reading the standard format data.

8.1.2 Software Environment

Operating system: Win7/Win10 operating system.

8.1.3 Network Condition

No less than 10M, it is suggested to use above 50M.

8.2 Security Software

Windows Defender, Windows operating system built-in firewall.

8.3 Data and Equipment (system) Interface

1. Test result can be updated in Autobio-ACD format with TPC/IP protocol through RJ45 interface.;

2. Test result can be updated in Autobio-ACD format with RS232 protocol through serial port;

3. The external barcode reader can be connected to the external barcode reader to obtain 1D/2D barcode information port connection through USB2.0, USB3.0 interface;

4. The removable storage device can be connected with the computer through USB2.0, USB3.0 interface;

5. Storage data format: ldf and mdf.

8.4 User Access Mechanism

Access control:

Windows users need to enter a password to log in;

Permission control:

The user privilege of the software is divided into three levels: operator, administrator, and maintainer.

Operator: General application and operation functions of the system, including initialization of the instrument, editing sample information, starting testing, viewing consumables

information, viewing test running status, viewing results, calibration management, quality control management, log viewing, shutdown and other functions.

First Class function	Second class function	Third class function	Operator	Administrator	Maintainer
System diagnosis	SRK Scan		×	√	√
	Liquid level test		×	√	√
	PCR Routine		×	√	√
	Quantitative		×	√	√
	Metering time		×	√	√
System settings	General settings		×	√	√
	Report settings		×	√	√
	Lis Communication settings		×	√	√
	Administrator		×	√	√
	Backup		×	√	√
	About		×	√	√
Maintenance	Maintenance	Real time backup	×	√	√
		Recovery system	×	√	√
		Clear historical data	×	√	√
	Clean	Daily clean	√	√	√
		Clean PCR	√	√	√
	Commissioning	Unit test	×	×	√
		Sensor lists	√	√	√
	System	Shutdown the system	√	√	√
		Close the softeare	√	√	√
		Reinitialization	√	√	√
		User switch	√	√	√
Test analysis	Consumables	Consumables	√	√	√
		Kits management	√	√	√

	Calibrator	Calibration	√	√	√
		Calibrator settins	√	√	√
	QC	QC	√	√	√
		QC settings	√	√	√
	Test request	Patient test request	√	√	√
		QC test request	√	√	√
		Calibration test request	√	√	√
	Test run	Request queue	√	√	√
		In process	√	√	√
		Abnormal queue	√	√	√
		Work pending	√	√	√
	Result analysis		√	√	√
Abnormal test			√	√	√
Pending			√	√	√
Kits			√	√	√
Consumables			√	√	√
QC			√	√	√
Log			√	√	√
Main interface			√	√	√
Test request			√	√	√
Fluorescent			√	√	√
Test result			√	√	√

8.5 Software Environment

Operating system: Windows7/ Windows 10 operating system.

Database: Microsoft SQL Server 2012 Express.

8.6 Update of Security Software

Complete security software updates through the operating system update push.

8.7 Remote Update of Client Software

After networking, if a new software version is detected, users can choose whether to upgrade the software to the new version.

CAUTION

1. When using antivirus program to eliminate viruses from the whole computer, the software may misjudge or delete content by mistake. Please be careful to the content under the software in antivirus and delete processing.

2. The U disk or other mobile devices inserted into the computer should be checked for viruses and treated with antivirus program. Beware of viruses that can infect your computer and affect your software.

3. In the process of historical data cleaning, data backup should be carried out in advance to prevent data from being deleted by mistake and resulting in unrecoverable data. The automatic upgrade function of the system should be turned off during the operation of the system to prevent data loss or system failure during the upgrade process, which will affect the operation of the device.

9 Appendix

Appendix 1- Table of Error Codes

Example: -21122510	
-21 12 251 0	
	Level 0: Serious (STOP) Level 1: General (affecting subsequent tests) Level 2: Notification (affecting only one test) Level 3: No affect
	Actual error cause
	PMC No./CAN ID
	The module number where the error occurred, the bottom layer is 20, 20 + unit modules

Error No.	Descriptions
1	The lower machine returns - Wrong Command ID - The action instruction number sent by the control machine to the lower machine does not exist.
2	The lower machine returns - Wrong Type ID -The action instruction type number sent by the control machine to the lower machine is out of range.
3	The lower machine returns - Wrong Value - The setting value sent by the control machine to the lower machine is out of range.
4	The lower machine returns - Invalid Command - The action instruction issued by the control machine will not be executed by the lower machine.

5	The lower machine returns - Operation Failed (Failed) - The lower machine failed to execute the action instruction issued by the control machine.
6	The lower machine returns -Busying -The lower machine is executing other action instructions, and the new received instruction will not be executed.
7	The lower machine returns -Wrong Subtype ID -The motor number, port number and parameter number issued by the control machine are wrong.
8	The lower machine returns -Fault (Error) -An exception has been detected on the lower machine.
9	The lower machine returns -Wrong CAN ID -The CAN ID of the control machine is inconsistent with the identification of the control machine in the CAN frame.
10	Motor parameters could not be found.
21	The CAN initialization is abnormal.
25	CAN reception is abnormal
26	Motor initialization fails.
27	The motor is not initialized.
28	The motor is not powered on.
29	The motor runs timeout.
30	Module is busy.
31	RFID reception occurs error.
32	Timeout of RFID exception occurs.
33	The STOP button has been pressed.
34	No origin restores.
35	The motor is not powered on.

36	Running timeout of the motor occurs.
37	The needle is blocked.
38	The stop sensor is triggered.
39	Motor action is not over.
40	Target pulse overstep the boundary.
41	The PCR tube dropped halfway.
42	The PCR unit cover fails to open.
43	The PCR unit cover fails to close.
48	The origin sensor of SPPZ is not triggered when RPPY is moving.
49	Air suction occurs.
50	RPPZ is not initialized when it moves.
51	When RPPX moves, the origin sensor of RPPZ is not triggered.
52	When RPPX moves, the origin sensor of RPPZ is not triggered.
53	Timeout of unit running occurs.
54	When the PCR was cleaned from the hole, the PCR unit fell off.
55	No Tips.
56	No PCR tubes.
57	No waste bucket.
58	Waste liquid exceeds the limit of waste liquid container.
59	Purified water is too little.
61	It fails to get the Tip.
62	It fails to discard Tip.
63	Peagent needle fails to grab PCR tube.
64	The motor is not in position.

65	The PCR transfer gripper fails to grab the cap.
66	When cleaning the PCR tube from the hole, grasping the PCR tube fails.
67	When the PCR tube was cleaned from the hole, PCR tube abandonment fails.
68	Waste line anomaly occurs.
69	Placement of the reagent needle into the PCR tube fails.
70	The PCR transfer gripper fails to place the cap.
71	Tip drops as it moves.
72	Y axis position of the PCR gripper is wrong.
73	X axis position of the PCR gripper is wrong.
74	Interference caused by the z-axis not returning to the origin occurs.
75	The target hole number of PCR is abnormal.
76	Float switch alarms.
77	No item parameters are found.

Appendix 2- Backtracking Authorization

Company:				Company: Autobio Diagnostics Co., Ltd.	
Address:				Address: No.199, 15th Ave National Eco & Tech Zone, zhengzhou 450016, China	
Contact				Consignee: Customer Service Center	
Tel				Tel: [86]-371-6798-5313	
Fax		Zip		Zip	450016

Fault description:

The accessories sent back together with the instrument are :

Precautions for the instrument packaging are as follows:

1. Please pack the instrument with the original packing box if it still exists.
2. Please pack the instrument with double layer packing if the original packing box does not exist.

a. Put the instrument in a box with foam in the bottom, and fill the side and top with foam, then seal the box to prevent damages caused by shocking during transportation.

b. After the first layer is finished, put it in a larger packing box and fill its four sides and top with foam.

c. Seal the outer packing box.

NOTE:

1. Please read the precaution of the instrument packaging carefully. Please fill the blanks in this annex and put in the box to be sent back together.
2. The instrument shall be disinfected in strict accordance with the "cleaning" method in the manual "maintenance and service" before being returned to the factory for packaging.

Appendix 3- Disinfection Statement

Product Name:	Serial No.:
Model:	Backtracking Authorization:
Purchase Date:	No. of Warranty Certificate:

A Does the internal or external of the product have ever been exposed to the following environment?

Please mark “yes” or “no” with X, then answer each of the questions below and give a detailed description in the B column.

	Yes	No		Yes	No
1 Pathological blood and body fluid			4 Chemical or material may endanger health		
2 Any other bio-hazardous substance			5 Radioactive material (please provide detail information below, including name, quantity and residual activity of the isotope)		
3 Substance that can decompose into dangerous substance			6 Other hazards		

B Inform detailed information about the harmful substances in the environment that the product has been exposed to, including the name, quantity and related safety analysis table:

NOTE: If harmful substances have been used, disinfection treatment must be done.

C Your disinfectant method (table can be attached) is :

D Whether are the substances mentioned in part A or B likely to remain contaminated?

I guarantee the truth and efficiency of the information provided above.

Sign:	Date:
Name:	Title:
Company:	
Address:	
Tel:	E-mail: