Negli ultimi anni, la tecnologia point of care (POCT) sta rivoluzionando il mondo della diagnostica medica.

Gli analizzatori di chimica clinica Pushkang rappresentano un eccellente esempio di come la tecnologia POCT stia cambiando il modo in cui la diagnostica medica possa essere eseguita, in particolare nelle farmacie.

Il Pushkang MS100 è un analizzatore di chimica clinica professionale semiautomatico, pratico ed estremamente compatto, che offre una soluzione rapida e precisa per la diagnosi di patologie comuni. Il dispositivo utilizza la tecnologia della spettrofotometria a trasmissione, che consente di analizzare campioni di sangue da capillare per determinare i livelli di vari composti biochimici come glicemia, colesterolo, trigliceridi, creatinina, acido urico e molto altro ancora. Questo aiuta a diagnosticare precocemente le patologie e a monitorare i pazienti in modo accurato.

Il dispositivo richiede solo una piccola quantità di campione biologico ed è dotato, inoltre, di una tecnologia di calibrazione automatica che garantisce la precisione dei risultati. È in grado di analizzare fino a 23 parametri diversi in un'unica sessione di test e i risultati possono essere ottenuti in appena 12 minuti.

Gli analizzatori sono stati progettati per essere facili da usare, anche da parte del personale delle farmacie senza particolare esperienza medica. Sono, infatti, dotati di un'interfaccia utente intuitiva che guida l'operatore attraverso tutte le fasi del test, dall'inserimento del campione alla visualizzazione dei risultati. Inoltre, gli analizzatori hanno un display a colori di alta qualità che consente di visualizzare in modo chiaro e dettagliato i risultati del test.

Un'altra caratteristica importante è l'interoperabilità con i sistemi informativi ospedalieri, medici e di laboratorio (LIS). Grazie a questo, i dati dei pazienti possono essere condivisi in modo sicuro e veloce con altri professionisti sanitari, consentendo una gestione coordinata delle cure e una presa in carico completa del paziente.

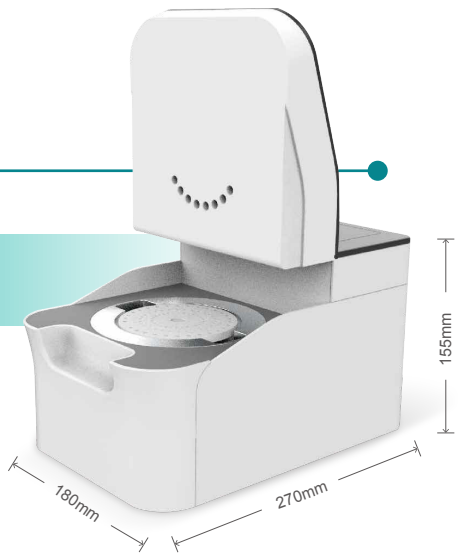
Inoltre, l'analizzatore Pushkang MS100 si inserisce perfettamente nel contesto dell'Industria 4.0, ovvero la quarta rivoluzione industriale che si basa sulla digitalizzazione e l'interconnessione dei processi produttivi e dei sistemi informatici. Questo dispositivo, infatti, è in grado di integrarsi con altri strumenti e applicazioni, migliorando l'efficienza dei processi e la qualità del servizio offerto al paziente.

Gli analizzatori Pushkang sono macchinari IVD per il solo uso professionale da parte di un farmacista, diversamente dai macchinari autotest finora utilizzati in farmacia. Utilizzano tecnologia microfluidica partendo da reagenti liofilizzati inseriti in pannelli test precaricati.

PUSHKANG

MS100
Analizzatore Chimico

Centrifugal microfluidic biochemical POCT test platform



- Scelta tra numerose combinazioni di reagenti per analisi cliniche complete
- Strumento di dimensioni compatte con schermo a colori e sistema Android
- Veloce, preciso e portatile

CE IVD ISO ISO13485 TÜVRheinland

Specifiche tecniche

Tipo di campione	Sangue intero, sangue capillare, plasma, siero
Principio del test	Colorimetria fotoelettrica
Connessione	On-line use of LIS system
Volume del campione	140μL
Test time	≤12min
Code identification	Utilizzo esterno di QR scanner, riconoscimento del disco reagenti tramite QR code
Temperatura di reazione	37±0.5℃
Light source	LED lamp
Stampante	Stampante termica incorporata e stampante esterna (driver della stampante wireless)
Sistema operativo	Android 5.1 (5-inch)
Memoria interna	1GB，expandable 32GB TF Card
Supply voltage	AC100V-240V，50-60HZ
Dimensioni	270mm*180mm*155mm
Peso	3KG，with built-in adapter

Pannelli test

Liver Function	TP ALB GLO* ALB/GLO* ALT AST GGT ALP TBIL DBIL IBIL*
Glucose and Lipid	TG CHOL HDL-C LDL-C* GLU GSP#
Renal Function	ALB CRE UREA UA Ca^{2+} PHOS CO_2
Electrolyte 7	K^+ Ca^{2+} Na^+ Cl^- CO_2 Mg^{2+} PHOS
General Chemistry 9	TP ALB TBIL CRE UREA GGT AST ALT GLU GLO* ALB/GLO*
General Chemistry 13	TP ALB ALT AST TBIL DBIL UA UREA CRE GLU TG CHOL HDL-C IBIL* LDL-C* GLO* ALB/GLO*
Emergency Room 13	AST CK CK-MB LDH α-HBDH GLU AMY CRE UA K+ Na+ Cl- CO2
Myocardial Enzyme	AST CK CK-MB LDH α-HBDH
Electrolyte 4	K+ Na+ Cl- CO2
General Chemistry 19	TP ALB ALP AMY CHE CK CRE UREA DBIL TBIL GLU TBA TC TG UA GGT ALT AST HDL-C IBIL* LDL-C* GLO* ALB/GLO* U/A*

**Calculated / GSP# means coming soon*

Istruzioni d'uso

Inserire disco

Aggiungere campione e diluente

Premere "start"

Risultato test

PUSHKANG

Easypharm SRL

EASYPHARM S.R.L
Via degli Olmetti, 5/B int. A22 00060 Formello (RM)
Tel. 06.9075226 – 06.90409154 - 06.31056284

Email：info@easypharm.it
Web：www.easypharm.it
Fax 06.92912957 — Nsis 008703

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 095100 0003 Rev. 04

Holder of Certificate: **Zhejiang Pushkang Biotechnology Co., Ltd**
C408, Science and Technology Innovation Park
No.398, Mahuan Road, Binhai new Area
312366 Shaoxing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents, Reagent Kits and Instruments for Immunohematology, Immunochemistry and Clinical Chemistry**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 095100 0003 Rev. 04

Report No.: SH22105401

Valid from: 2022-09-07
Valid until: 2025-09-06

Date, 2022-09-07

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 095100 0003 Rev. 04

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Zhejiang Pushkang Biotechnology Co., Ltd
C408, Science and Technology Innovation Park, No.398, Mahuan Road, Binhai new Area, 312366 Shaoxing, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

CE

DECLARATION OF CONFORMITY

Manufacturer:	Zhejiang PushKang Biotechnology Co., Ltd.
Address:	C408, Science and Technology Innovation Park NO.398, Mahuan Road, Binhai new Area, 312366 Shaoxing, Zhejiang, PEOPLE'S REPUBLIC OF CHINA.
EC Representative:	Medwheat Tech Service GmbH
Address:	Max-Planck-Straβe 4 85609 Aschheim b. München Germany
Product Name:	Chemistry Analyzer (MS100) General Chemistry 9 Test Panel General Chemistry 13 Test Panel Emergency Room 13 Test Panel Electrolyte 7 Test Panel
Classification：	Others (IVDD), only for professional use
Conformity Assessment Procedure:	Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019	EN ISO 18113-1:2011	EN ISO 18113-2:2011
EN 13612:2002+AC:2002	EN ISO 23640:2015	EN 13641:2002
EN ISO 20417: 2021	EN ISO13485:2016	

Shaoxing/China Oct. 15th 2021	Bo Yu, GM
Place, date	Name and function

ZHEJIANG PUSHKANG BIOTECHNOLOGY CO., LTD 浙江普康生物科技有限公司 3306021006073 8

CE

DECLARATION OF CONFORMITY

Manufacturer:	Zhejiang PushKang Biotechnology Co., Ltd.
Address:	C408, Science and Technology Innovation Park NO.398, Mahuan Road, Binhai new Area, 312366 Shaoxing, Zhejiang, PEOPLE'S REPUBLIC OF CHINA.
EC Representative:	SUNGO Cert GmbH
Address:	Harffstr. 47,40591 Düsseldorf, Germany
Product Name:	General Chemistry Panel Test I General Chemistry Panel Test II Liver Function Panel Test Renal Function Panel Test Myocardial Enzyme Panel Test Glucose and Lipid Panel Test
Classification：	Others (IVDD), only for professional use
Conformity Assessment Procedure:	Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

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EN ISO 20417: 2021	EN ISO13485:2016	

Shaoxing/China, Apr. 7th 2022	Bo Yu, GM
Place, date	Name and function

CE

Chemistry Analyzer
Instruction for Use
（Type：MS100）

Zhejiang PushKang Biotechnology Co.,Ltd.

Content

Preface

1. Description

Thank you for purchasing the MS100 Chemistry Analyzer！ Read all product manuals and consult with Pushkang trained personnel before you operate the system. Do not perform any procedure before you carefully read all instructions. Always follow the product labels and the recommendation from the manufacturer. For more information, contact Pushkang.

2. Basic Information

- Product name: Chemistry Analyzer
- Specifications and models：MS100
- Size：270mm×180mm×155mm
- Weight：3kg
- Range of application: It is used in conjunction with the chemistry kit produced by our company for the quantitative analysis of analytes in human samples. This instrument is suitable for laboratories with professional testing capabilities in medical institutions, such as central laboratories, outpatient and emergency laboratories, clinical departments, physical examination centers. For in vitro diagnostic use only.
- Contraindication: none

3. Index of Symbols

The following symbols are used on the chemistry analyzer, related components and accessories, labels or in the text of this user manual:

	Warning; Electricity
	Warning; Biological hazard
	Warning; Caution!
	In vitro diagnostic medical device
	Serial number
	Date of manufacture

	Consult instructions for use
	Manufacturer
	Authorized representative in the European Community
	This way up
	Fragile, handle with care
	Keep away from rain
	Stacking limit by number

4. Warnings and Precautions

Pay attention to and observe all warning labels attached to this instrument, do not cover or remove labels. If the label falls off or is blurred, please inform the after-sales service agency or agent of Pushkang to replace it.

【Waste Management】

- All used reagent disks should be treated as infectious waste.
- Some wastes may need special treatment before they are discarded. For waste treatment methods, please follow the relevant guidelines for medical waste, infectious waste and industrial waste implemented by the competent authorities of the country and region.
- Instruments may require special treatment before they are scrapped. For waste treatment methods, please follow the relevant guidelines for medical waste, infectious waste and industrial waste implemented by the competent authorities of the country and region.

Note: MS100 instruments should be regarded as industrial waste after being discarded, it should be specially managed as infectious waste in accordance with the waste treatment and public cleaning law. Before the instrument is discarded, it must be handled properly according to the relevant laws of the country and region where it is located.

【Prevent Fire and Damage】

- Install the instrument correctly according to the installation environment and conditions described in this manual.
- This instrument shall be installed by authorized personnel of Pushkang.
- If you need to change the installation of this instrument, please contact the after-sales service agency or agent.
- Do not use any flammable or flammable gas near the instrument to avoid explosion.
- Do not trample, twist, pull wire and cable, avoid to cause fire.
- If the equipment is not used according to the method specified by the manufacturer, the protection provided by the equipment may be destroyed.

【Prevent Infection】

- Please wear appropriate protective equipment when handling samples, performing maintenance operations, and handling waste.
- All patient samples should be treated as a potential source of infection. Please wear protective gear and follow general precautions in local or national regulations.
- If the user's skin touched the patient's sample, rinse the contact area with water. If necessary, go to the hospital in time.
- Wipe away any contaminants sprinkled on the instrument in time
- If you accidentally swallow any reagent or sample, please go to the hospital immediately.
- If hazardous substances (pollutants such as reagents or samples) leak on the surface or enter the inside of the equipment, should take appropriate disinfection measures.
- It is not allowed to use cleaning agents or disinfectants, such as alcohol, gasoline and other flammable organic solvents, which cause danger due to chemical reaction with equipment parts or materials contained in the equipment.
- If you have any questions about the compatibility of disinfectant or cleaning solvent with equipment parts or materials contained in the equipment, please contact our after-sales service agency or agent.

【Prevention of Personal Injury and Serious Injury】

- You can't start operating instruments until the cabin covers are closed
- Do not put your fingers or hands inside any opening.
- Do not touch any moving parts while the instrument is running.
- Do not look directly at the lens of the scanner. Looking directly at the scanner can cause eye injury.

【Instrument Operation Instructions】

- Install and operate instruments according to instructions, the instrument model applicable to this manual is: MS100.
- The operator of the instrument shall be the professional trained inspection personnel of medical and health institutions, and the relevant personnel shall be professionally trained to operate the instrument.
- Do not place the instrument in a position that is difficult for personnel to operate.
- When handling the instrument, it should be gently picked up by both sides and released after being placed in the predetermined position.
- The instrument should be installed on a stable operating table and close to a power socket with good ground connection.
- Dust may accumulate on the surface of the instrument after long-term storage. Wipe the surface gently with a clean soft cloth, and use a small amount of cleaning solvent if necessary. Cut off the power before cleaning the instrument. Cover the instrument when it is not in operation.
- This instrument is a closed type, please use it together with the matching detection reagent produced by Pushkang.
- Refer to the relevant instructions for the use and storage of reagents, quality control products and calibration products. In order to ensure the stability and reliability of the results, please use the reagents, quality control products and calibration products within the expiry date.
- Please follow the procedure described in this manual to operate the instrument, improper operation may produce incorrect results or lead to instrument failure.
- The instrument should be regularly maintained in strict accordance with the provisions of this manual, otherwise it may lead to instrument failure or affect the accuracy and precision of instrument testing.
- Users are not allowed to disassemble or replace any parts of the instrument by yourselves. If you need to replace or repair, please contact our after-sales service agency or agent for operation by the after-sales service engineer.
- If the result of retest is still out of control, please contact our after-sales service agency or agent immediately.

【Electromagnetic Compatibility and Noise】

- Don't place the instrument beside the equipment that produces great electrical noise.
- Electromagnetic waves will be generated during the use of the instrument. Please keep away from the instrument sensitive to electromagnetic waves.
- The instrument meets the emission and immunity requirements specified in this part of EN 61326-1：2013 and EN 61326-2-6：2013, as shown in the table below.
- The users have the responsibility to ensure the EMC environment of the equipment, so that the equipment can work normally.
- It is recommended to evaluate the electromagnetic environment before using the equipment.
- The instrument is designed and tested according to group 1, class A equipment in CISPR 11：2016. In the home environment, this equipment may cause radio interference, so it is necessary to take protective measures.

- It is forbidden to use the equipment near strong radiation sources (such as unshielded RF sources), otherwise it may interfere with the normal operation of the equipment.

The instrument electromagnetic compatibility disturbance test shall meet the following requirements:

Table 1 EMC emission test requirements

Electromagnetic emission		
Normative Reference	Test Item	Compliance
CISPR 11：2016	Conducted emission	Group 1, class A
CISPR 11：2016	Radiated emission	Group 1, class A
IEC 61000-3-2：2018	Harmonic current emission	NA
IEC 61000-3-3：2017	Voltage fluctuation and flicker	NA

The EMC immunity test of the instrument shall meet the following requirements:

Table 2 EMC immunity test requirements

Electromagnetic Immunity			
Test Item	Normative Reference	Trial value	Compliance with performance criteria
Electrostatic discharge (ESD)	IEC 61000-4-2-2008	±2kV,±4kV contact discharge ±2kV, ±4kV, ±8kV air discharge	B
Electromagnetic field	IEC 61000-4-3:2010	3V/m（80MHz～1GHz） 3V/m（1.4GHz～2GHz） 1V/m（2GHz～2.7GHz）	A
Burst	IEC 61000-4-4:2012	AC power: ±1kV(5/50ns,5kHz)	B
Surge	IEC 61000-4-5:2017	Line to ground: ±2kV Line to line: ±1kV	B
Conducted RF	IEC 61000-4-6:2013	3V，150kHz～80MHz, 80%AM	A
Power frequency magnetic field	IEC 61000-4-8:2009	3A/m，（50 Hz，60Hz）	A
Voltage dip and interruption	IEC 61000-4-11:2017	1 cycle 0%; 5/6 cycle 40%; 25/30cycle70%; 250/300 cycle 5%;	B C C C

Compliance criterion:

Performance criterion A: The equipment shall continue to operate as intended during and after the test. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer,when the equipment is used as intended.The performance level may be replaced by a permissible loss of performance.lf the minimum performance level or the permissible performance loss is not specified by the manufacturer,either of these may be derived from the product description and documentation and what the user may reasonably expect from the equipment if used as intended.

Performance criterion B: The equipment shall continue to operate as intended after the test. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer, when the equipment is used as intended.The performance level may be replaced by a permissible loss of performance. During the test. degradation of performance is however allowed. No change of actual operating state or stored data is allowed.lf the minimum performance level or the permissible performance loss is not specified by the manufacturer, either of these may be derived from the product description and documentation and what the user may reasonably expect from the equipment if used as intended

Performance criterion C: Temporary loss of function is allowed, provided the function is self-recoverable or can be restored by the operation of the controls

1. Summary of Instrument

Thank you for choosing the MS100 Chemistry Analyzer! Our company will send engineers to install and train the users. The operators should be the inspectors of medical and health institutions who have received professional training. The relevant personnel must receive professional training to operate the instrument.

1.1 Intended Use

The MS100 Chemistry Analyzer is used in conjunction with the chemistry kit produced by Zhejiang PushKang Biotechnology Co., Ltd. for the quantitative analysis of analytes in human samples. This instrument is suitable for laboratories with professional testing capabilities in medical institutions, such as central laboratories, outpatient and emergency laboratories, clinical departments, physical examination centers. For in vitro diagnostic use only.

1.2 Operating Principle

Chemistry analyzer uses spectrophotometric method, its working principle is as follows: add sample to test hole containing lyophilized reagent, by centrifugation at high speed. After the reaction, a beam of monochromatic light is pierced into the tested liquid, and the optical signal passing through the tested liquid is converted into an electrical signal. The signal is converted and processed properly, then the concentration of the tested liquid can be obtained by referring to the standard curve.

1.3 Working Conditions

Power voltage:	~220V-240V, 50/60Hz
Rated power:	100VA
Environment temperature:	15℃~30℃
Relative humidity:	40%~85%
Atmospheric pressure:	85.0kPa～106.0kPa
Stay away from interference source of strong electromagnetic field;	
Avoid direct exposure to strong light;	
Well-ventilated environment;	
With good grounding;	

1.4 Performance

<table>
<tr><td>Stray light</td><td>The absorbance is not less than 2.3.</td></tr>
<tr><td>Absorbance linearity</td><td>The maximum absorbance within ±5% relative bias shall not be less than 2.0.</td></tr>
<tr><td>Accuracy of absorbance</td><td>Should meet the requirements in the following table.
<table>
<tr><th>Absorbance</th><th>Allowable error</th></tr>
<tr><td>0.5</td><td>±0.025</td></tr>
<tr><td>1.0</td><td>±0.07</td></tr>
</table></td></tr>
<tr><td>Stability of</td><td>The change in absorbance should not be greater than 0.01.</td></tr>
</table>

<table>
<tr><td>absorbance</td><td></td></tr>
<tr><td>Repeatability of absorbance</td><td>Expressed by the coefficient of variation, it should not be greater than 1.5%.</td></tr>
<tr><td>Temperature accuracy and fluctuation</td><td>The temperature value is within ±0.3℃ of the set value, and the fluctuation is not more than ±0.2℃.</td></tr>
<tr><td>Intra-assay precision in clinical laboratories</td><td>The coefficient of variation (CV) should meet the requirements in the following table.
<table>
<tr><td>Item</td><td>Concentration range</td><td>Coefficient of variation requirement/%</td></tr>
<tr><td>Alanine aminotransferase(ALT)</td><td>30U/L~50U/L</td><td>CV≤5</td></tr>
<tr><td>Urea (UREA)</td><td>7.0mmol/L~11.0mmol/L</td><td>CV≤2.5</td></tr>
<tr><td>Total protein (TP)</td><td>50.0g/L~70.0g/L</td><td>CV≤2.5</td></tr>
</table></td></tr>
<tr><td>Appearance</td><td>· The appearance should be clean without scratch, burr and other defects;
· The graphic symbols and words on the panel shall be accurate, clear and uniform;
· The connection of fasteners shall be firm and reliable without looseness
· The moving parts should be stable, and should not be stuck, jump and significant empty return. The key group should be flexible.</td></tr>
<tr><td>Function</td><td>The instrument has the following main functions:
· The instrument has a self-check function;
· Prompt function: There should be corresponding prompts for replacement of light source components, abnormal absorbance, test completion or error;
· Software function: should include quality control, record, setting, help, test interface;
· User management: should include user identification methods and user types and permissions;
· Communication function: The instrument should have 2 RS232 serial ports, 1 USB interface and 1 LAN interface; the instrument has WiFi connection function.</td></tr>
<tr><td>Safety Requirements</td><td>Should meet the requirements of EN61010-1: 2010+A1：2019、EN 61010-2-101：2017.</td></tr>
<tr><td>Electromagnetic Compatibility</td><td>Should meet the requirements of EN 61326-1：2013 and EN 61326-2-6：2013.</td></tr>
</table>

1.5 Software System

Software Edition Number：

Name of the software: MS100 chemistry analyzer software, software edition number: V1.0.

Operating Condition：

Operating system:	Android5.1 or above
Ramer:	1024M
Internal storage memory:	8G

Monitor resolution:	1280×720
Monitor resolution:	1280×720
Lower computer system:	dsPIC33
Random access memory:	1M

Data Interface:

RS232 serial port, USB connector, LAN port.

User Access Control:

User identification method	User name, password
User types	Administrator and ordinary user
User permissions	The administrator has all the operation permissions of the system, and ordinary users can only carry out test related operations.

1.6 Sample Type

Whole blood, plasma, serum.

1.7 Applicable Reagents

It should be used together with the chemistry kit produced by Zhejiang Pushkang Biotechnology Co., Ltd.

Kit name	Project name
Chemistry 9 Test Panel	ALB, TP, TBIL, Crea, Urea, GGT, AST, ALT , GLU
Chemistry 13 Test Panel	TP, ALB, ALT, AST, TBIL, DBIL, UA, Crea, Urea, GLU, TG, CHOL, HDL-C
Emergency Room 13 Test Panel	AST, UA, Crea, GLU, CK, CK-MB, LDH, α-HBDH , AMY, K^+, Na^+, CL^-, CO_2
Electrolyte 7 Test Panel	K^+, $Ca2^+$, Na^+, CL^-, CO_2, P

1.8 Transportation and Storage Requirements

Transportation Requirement:

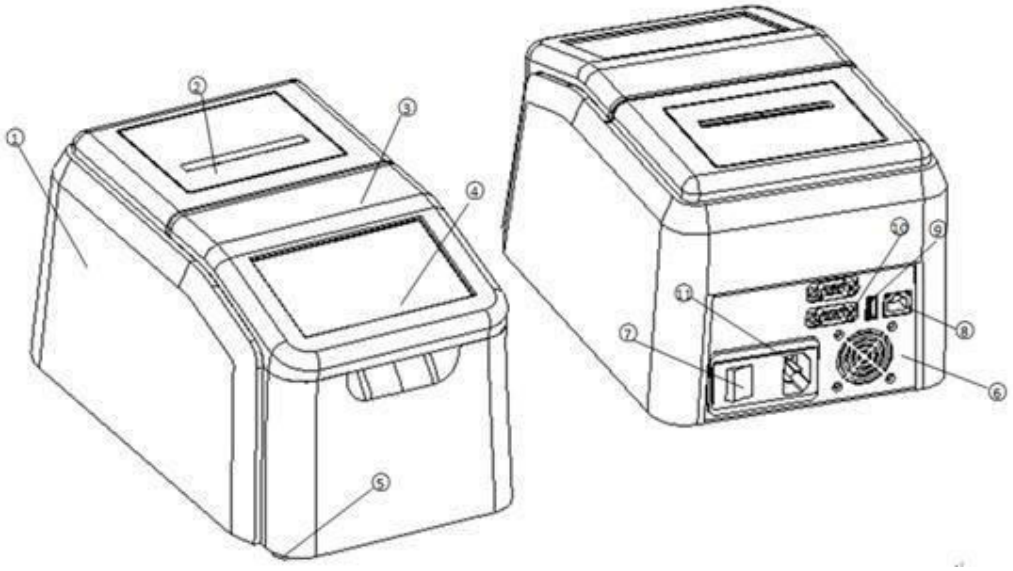
The packed MS100 chemistry analyzer can be transported by general means to prevent violent vibration, moisture and sun exposure. It is strictly forbidden to turn upside down and tilt. It should be moved gently during transportation to ensure that the products are delivered to customers in good condition.

Storage Requirements:

After packaged, the instrument should be stored in a well ventilated environment with - 20℃~ 55℃, relative humidity no more than 70%, no corrosive gas.

1.9 Product Structure

MS100 chemistry analyzer is composed of detector, microprocessor, touch screen and printer.



1.7-1 Integral structure

1. body shell 2. printer 3. top cover 4. touch screen 5. foundation
6. back plate 7. power switch 8. LAN connector 9. USB connector
10. RS232 connector 11. power port

2. Installation Instructions

When you receive the instrument, follow the instructions below to receive and install it:

2.1 Receiving Guide

- Please check whether there are visible cracks, dents or possible damage caused by transportation around the packing box of the instrument. If you find any visible cracks, dents or possible damage caused by transportation, please contact our after-sales service agency or agent in time.
- After receiving the instrument, please check whether the package is in good condition. If the instrument may be damaged, please contact the person in charge of the entrusted transportation company immediately.
- When you receive the instrument, please inform our after-sales service agency or agent immediately, and make an appointment for application engineer or maintenance engineer to open and install it.

2.2 Packing List

After opening the package of chemistry analyzer, please check whether the items are damaged according to the list in table 2.

Table 2 Packing list

Items	Quantity
Chemistry analyzer	1
Power line	1
Barcode scanner	1
Thermal printing paper	1
Production certification	1
Instruction for use	1
Warranty card	1

2.3 Installation Environment

2.3.1 Requirements for Using Environment

- Environment temperature: 15℃~30℃;
- Relative humidity: 40%~85%;
- Altitude: Below 2000 meters;
- Atmospheric pressure: 85.0kPa～106.0kPa；
- It should be placed in a stable worktable, far away from the interference source of strong electromagnetic field, avoid direct illumination of strong light, and in a well-ventilated environment with good grounding.

2.3.2 Peripheral Environmental Requirements

In order to facilitate the operation, maintenance and repair of the instrument, the installation of Chemistry analyzer should meet the following conditions:

- The distance between the left and right sides of the instrument and the wall should not be less than 20cm;
- The distance between the back panel of the instrument and the wall should not be less than 20cm;
- The distance between the front of the instrument and other instruments should not be less than 20cm;
- The load-bearing capacity of the operating table for placing the instrument shall not be less than 10kg.

2.3.3 Power Requirement

- Power voltage: ~220V-240V;
- Rated frequency: 50/60Hz;
- Rated power: 100VA;
- The instrument should be close to the power socket and have good grounding.

2.4 Installation

2.4.1 Instrument Placement

When the instrument is placed on the horizontal console lightly, it should be ensured that the console is flat and the bearing capacity is not less than 10kg.

2.4.2 Computer Connection

If you need to connect the computer, use the communication cable to directly connect the RS232-1 interface.

2.4.3 Power Connection

The power socket used by the instrument must have grounding wire, and the socket must be stable and reliable in contact; all the required grounding points must be compulsorily grounded. First connect the interface of the power cord with the power interface of the instrument, and then plug one end of the power cord into the AC power socket.

2.4.4 Scanner Gun Connection

Before starting the instrument, connect the RS232 interface of the connecting line of the code scanning gun directly with the RS232-2 interface of the instrument.

Note: If the scanning gun is connected after the instrument is turned on, the scanning gun will not be able to identify the barcode. This scanning gun only supports the use of connected instrument, does not support wireless use after charging.

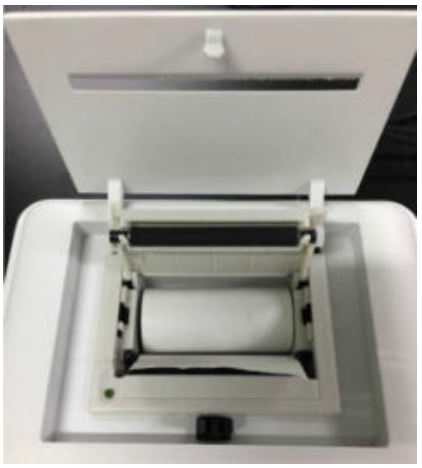
2.4.5 Installation of Thermal Printing Paper

Gently press the bottom of the printer cover, open the printer cover and the green indicator light is always on; pull up the left buckle and open the paper bin cover, and the green indicator light is flashing; take out the empty paper roll and put in the new thermal printing paper roll, pull

out a small section of it and insert it into the printer cover slot; close the paper bin cover and the printer cover in turn.

Note: When installing the thermal printing paper, the paper output end is close to the display screen. Please confirm that the installation is correct, or the instrument will not be able to print the test results normally.

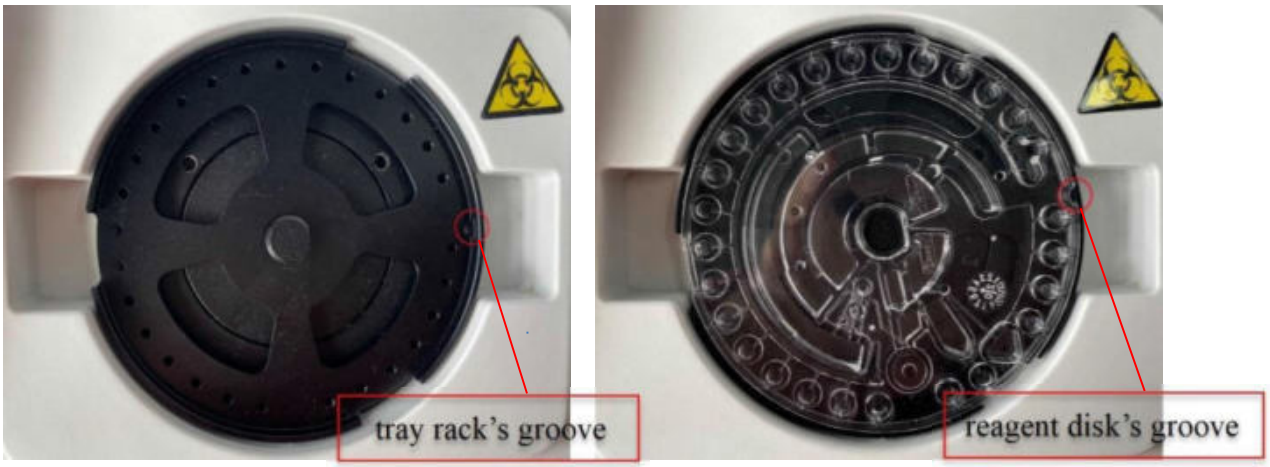
The installation style is shown in 2.4-1：



2.4-1 Printing paper installation diagram

2.4.6 Installation of Reagent Disk

Align the groove of the reagent disk with the groove of the tray rack, and gently press to fix the reagent disk.



2.4-2 Diagram of reagent disk installation

3. Operating Instructions

3.1 Pre-startup Inspection

- Make sure the power cord is properly connected.
- Make sure the scanning gun is connected correctly.
- Confirm thermal printing paper allowance.

3.2 Start-up System

After correctly connecting the power cord and the code scanning gun, turn on the power switch on the back of the instrument. The company logo will appear on the interface of the instrument and enter the self-inspection procedure, as shown in figure 3.2-1. Please wait patiently for the instrument to complete the self-inspection. After the instrument self-test is successful, it will enter the login interface. Please enter the ID and password and click “LOG IN” to enter the main interface, as shown in figure 3.3-1. If the self-test fails, please restart the instrument and make it self-test again. If it still fails, please contact our after-sales service agency or agent.

Figure 3.2-1 Instrument self-check and login interface

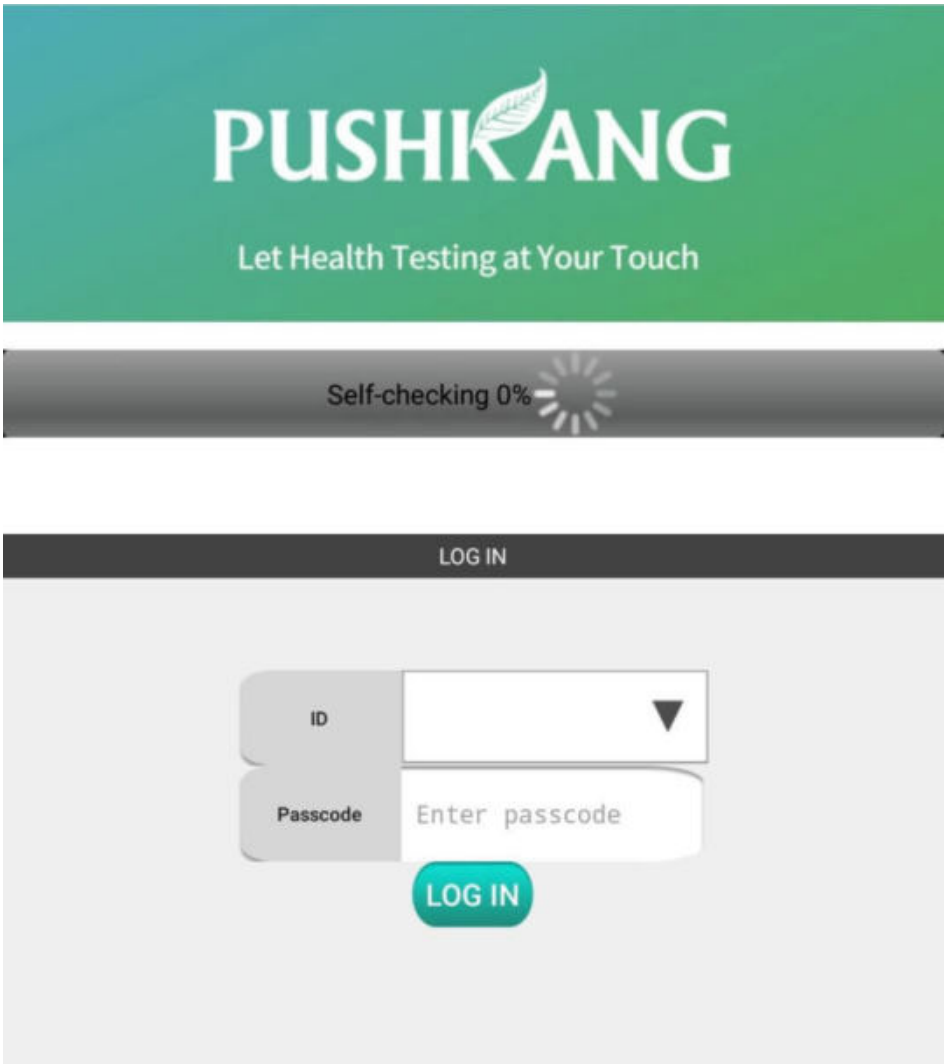


Figure 3.2-1 Instrument self-check and login interface

3.3 Main Interface

The top right part of the main interface is the time and date, the bottom left part is the software version number, and the middle part is the function area, which includes five parts: “QC”, “Record”, “Test”, “Settings” and “Help”.

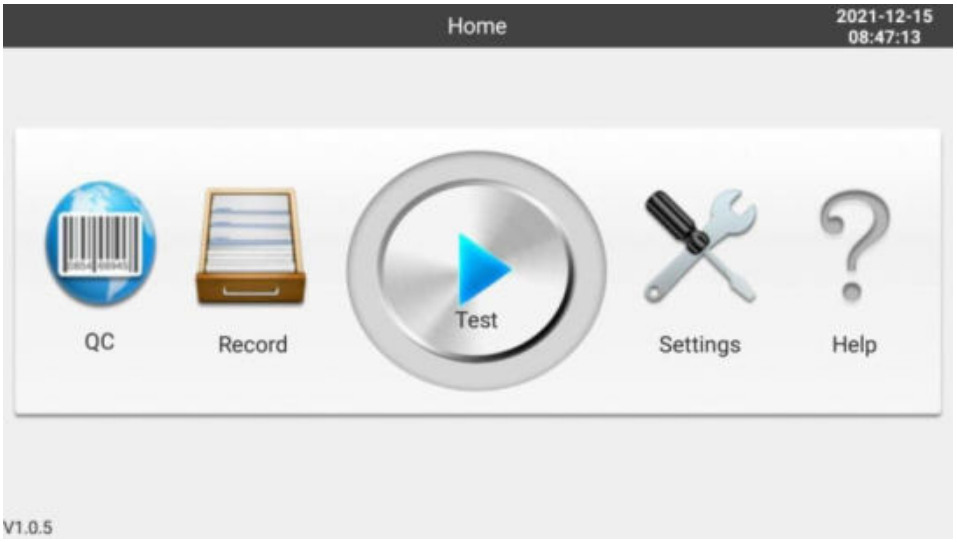


Figure 3.3-1 Main interface

3.4 Test

Before the formal test, please preheat the instrument for about 30 minutes. If the temperature does not reach the expected temperature due to insufficient preheat or other reasons, the instrument will alarm and cannot start the test.

3.4.1 Normal Test

After preheating, click the "Test" button. The interface will have the prompt of "Scanning", as shown in figure 3.4-1. Scan according to the prompt. To return, please click the return button in the upper left corner.

Figure 3.4-1 Scan reagent disk bar code prompt

After scanning, the system will automatically read the reagent disk information and jump to the patient information input interface, as shown in figure 3.4-2. Please confirm the test item, if it is correct, please click the "CONTINUE" button, if it is wrong, please "CANEL".

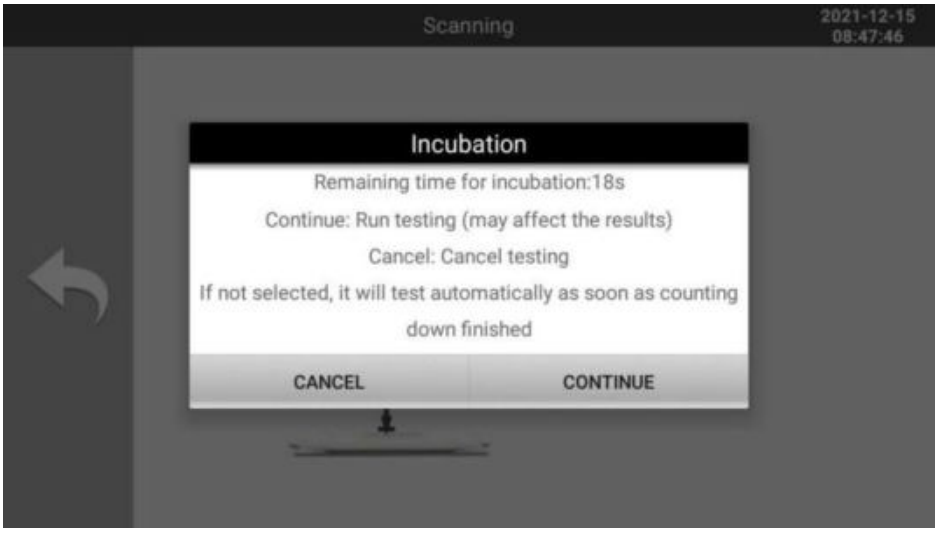


Figure 3.4-2 Test item determination interface

After clicking the "Confirm" button, the system will enter the test preparation prompt interface, as shown in figure 3.4-3, then operate according to the interface prompt.

Take out the reagent disc from the aluminum sealed bag, open the upper cover of the instrument, and put the test disc horizontally to the tray rack, then use the micro-pipette or other sample adding equipment, inject the sample into the reagent disc through the "Sample" sampling hole; inject the diluent into the reagent disc through the "Diluent" sampling hole; please refer to the reagent manual for the sample amount. Close the upper cover and click the  button to test.

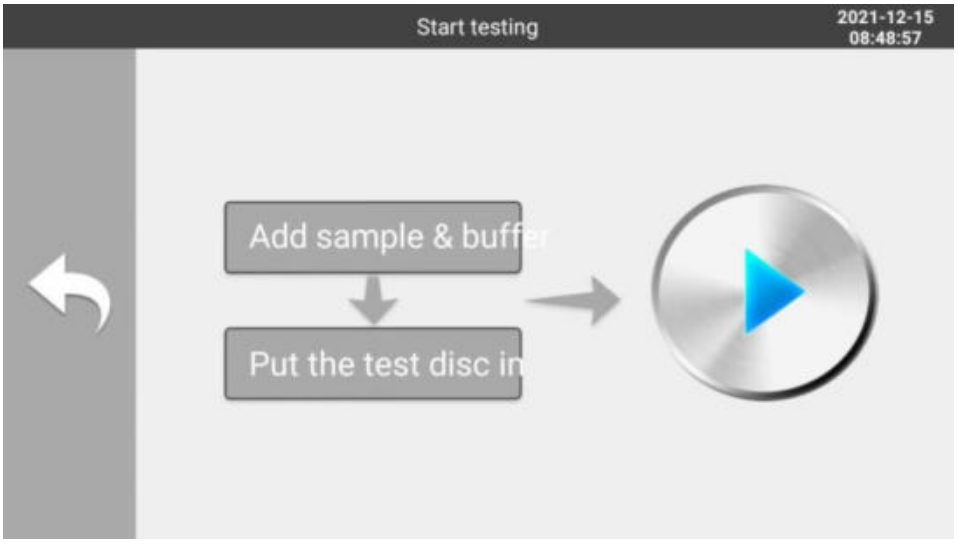


Figure 3.4-3 Test preparation prompt interface

Warning: Please wear dust-free gloves for operation, as the dust will cause destructive effects on the optical elements of the instrument. During and after sample addition, the test disk must be kept horizontal. Please place the reagent disk on the horizontal desktop for sample addition. When placing the test disk, please hold the edge of the disk and do not touch other parts of the disk.

The instrument starts testing, and the software enters the sample information input interface, as shown in Figure 3.4-4, enter the sample number and name in sequence; after confirmation, select gender and enter age in sequence.

Figure 3.4-4 Sample information input interface

After confirmation, wait for the test result, the interface is shown in Figure 3.4-5.

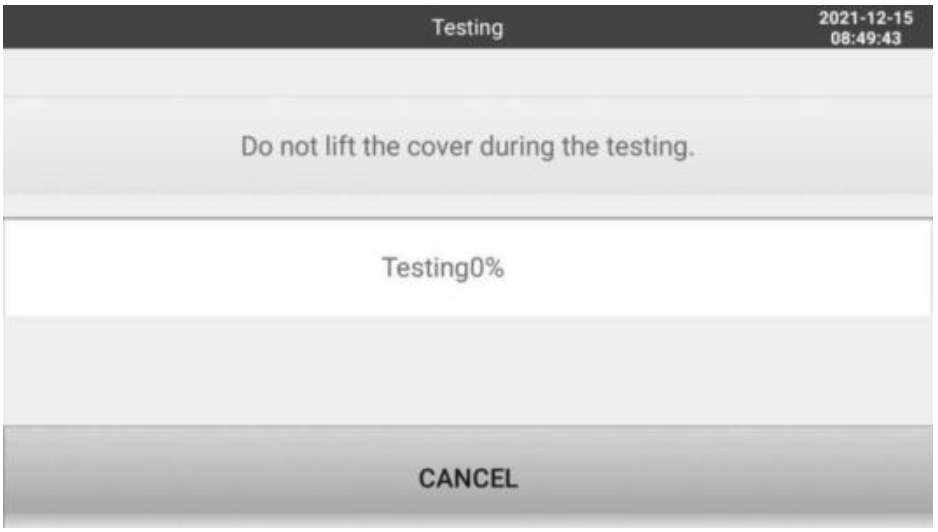


Figure 3.4-5 Testing process interface

After the test is completed, the test results will be displayed, as shown in figure 3.4-5, and the test results will be automatically saved in the internal memory of the analyzer. Click the print button on the top left of the interface to print the test results directly.

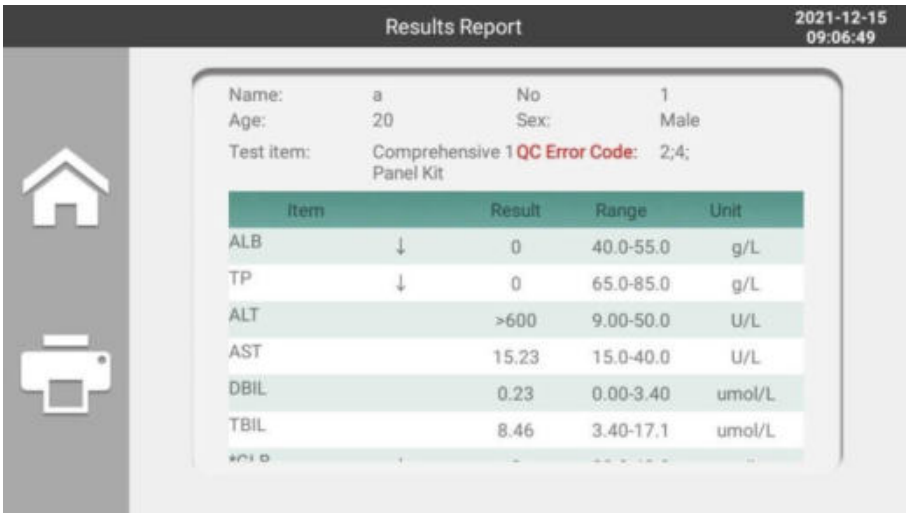


Figure 3.4-6 Test result interface

Note: Do not open the upper cover during the test. If the upper cover is opened due to mis-operation, the disk will stop running and the screen will display an alarm. This test will be invalid. Please take back the disk and dispose it as scrap. If you need to continue the test, please restart the test according to the normal test process.

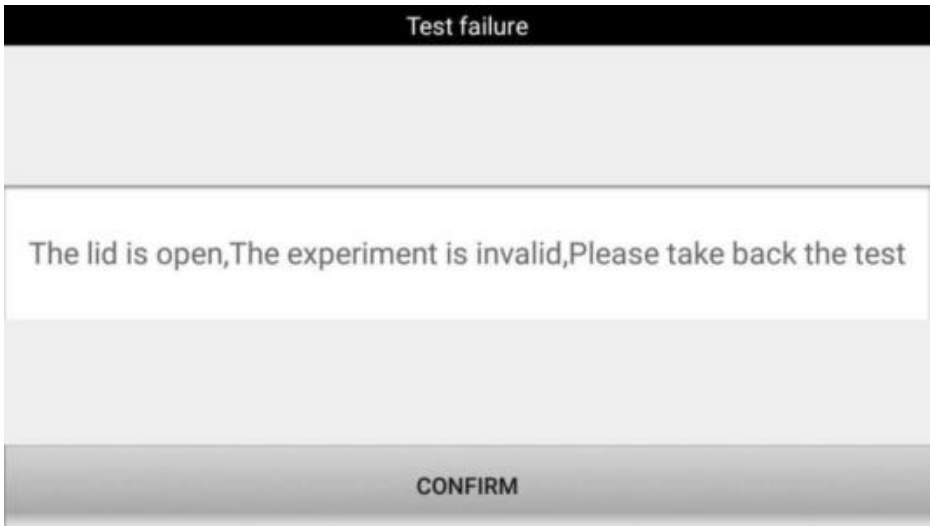


Figure 3.4-7Alarm for opening the lid

3.4.2 Cancel Detection

In the detection process interface, click the "Cancel" button, and "Cancel testing or not?" will pop up in the dialog box, click "OK" to cancel to cancel the detection, as shown in figure 3.4-6. The user takes out the disk and processes it according to the waste requirements, and then click "Conform" to return to the main interface.

Note: The reagent disk is a disposable product. The disk after use should be specially managed as infectious waste according to the waste treatment and public cleaning law.

Figure 3.4-8 Whether to cancel the detection interface

3.5 Quality Control

If it is necessary to conduct quality control test on the reagent disk, you can select the "QC" button in the main interface and use the quality control products provided by our company to replace the samples for test. The follow-up operation process is consistent with the routine test. The quality control chart can be viewed after the quality control test is completed.

3.6 Record

If the user needs to check the previous test data, click the "Record" button in the main interface to enter the historical data query interface, as shown in figure 3.6-1. The query results of "QC", "DATE" or "ID" can be selected according to the requests.

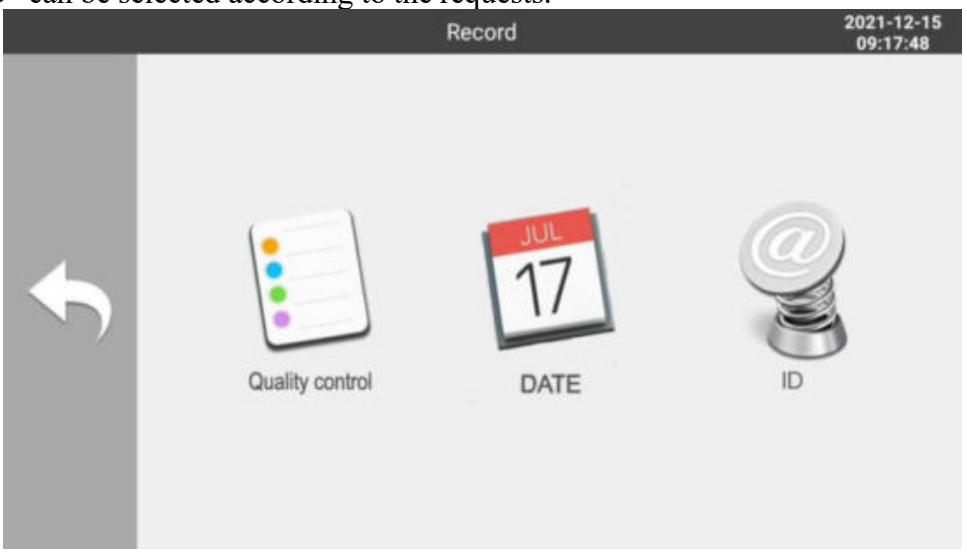


Figure 3.6-1 Record interface

3.6.1 Quality control query

Click the "Quality control" button on the record interface to enter the quality control result query interface. You can query by date. The query time range includes today, the recent week, and the recent month. Users can set the start date and end date in the custom interface according to their needs for inquiries. You can query the result interface within the corresponding time range, select the result you want to view and click to view the test result, as shown in Figure 3.6-2, you can print the result on the test result interface.

Figure 3.6-2 Quality control query interface

3.6.2 Date Query

In the record interface, click the "DATE" button to enter the test result query interface,as shown in

figure 3.6-2. The query time range includes today, recent week and recent month ect. Users can set the start date and end date to query according to their needs in the user-defined interface. The specific operation is the same as quality control query.

3.6.3 ID Query

Click the "ID" button in the record interface to enter the ID query interface, as shown in figure 3.6-3. You can input the ID to accurately query the test results.

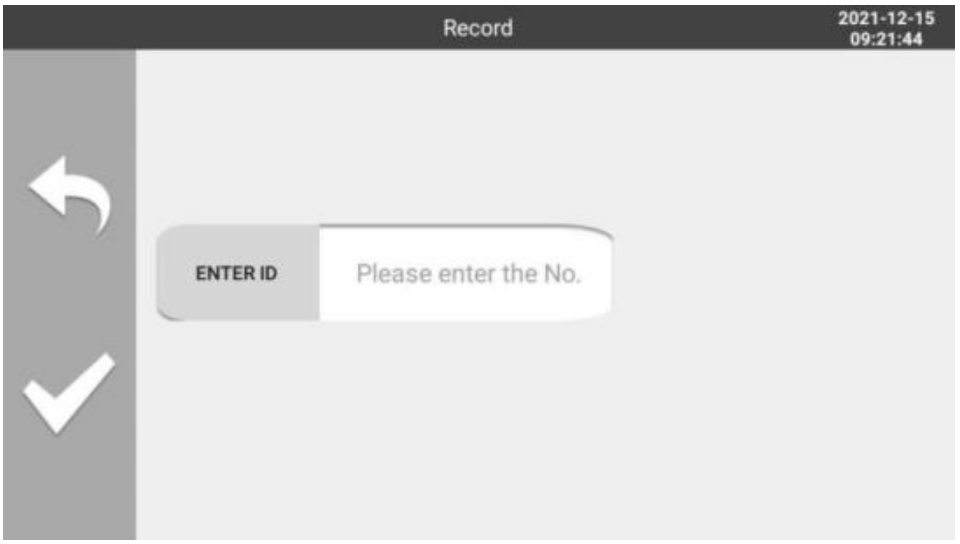


Figure 3.6-3 ID query

3.7 Setting

Click the "Settings" button in the main interface to enter the settings interface, where you can view "Device info.", "Brightness", "Network settings" , "Export logs", "Admin Mode" and "Name of hospital", as shown in figure 3.7-1.

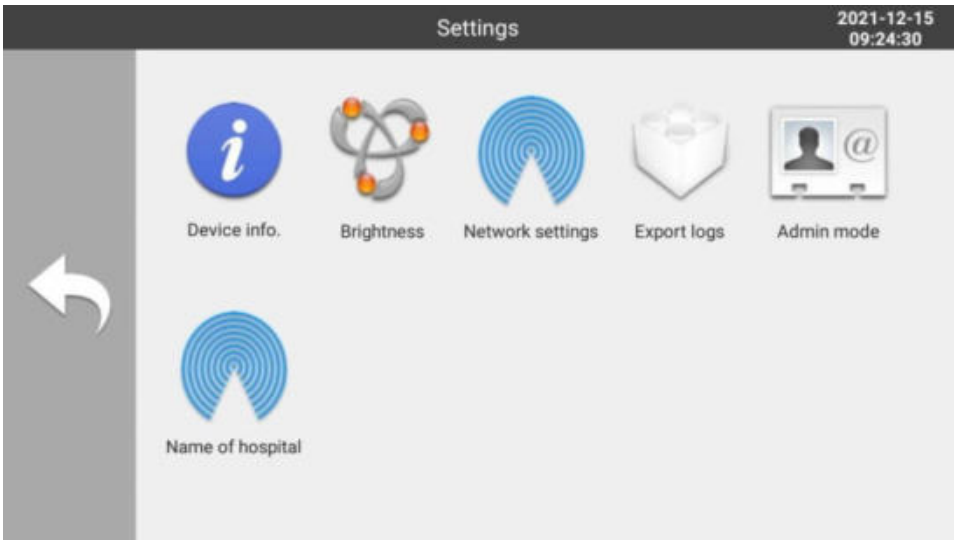


Figure 3.7-1 Setting interface

View Device Information

Click the "Device info." button in the setting interface to enter the device information interface to

view the device information.

Figure 3.7-2 Device Information Interface

Adjust Brightness

Click the "Brightness" button in the setting interface to enter the screen brightness adjustment interface to adjust the screen brightness.

Figure 3.7-3 Brightness adjustment interface

Network Settings

The instrument can choose to connect to the network through the LAN port and WiFi, and click the "Network Settings" button on the setting interface to perform network settings.

Click the "WiFi" button, select the network to be connected and enter the corresponding password to connect to WiFi.

Click the "Network Port" button to set the network port, as shown in Figure 3.7-4. When the instrument is connected to a valid IP address, the log record can be transmitted to the host where the IP address is located.

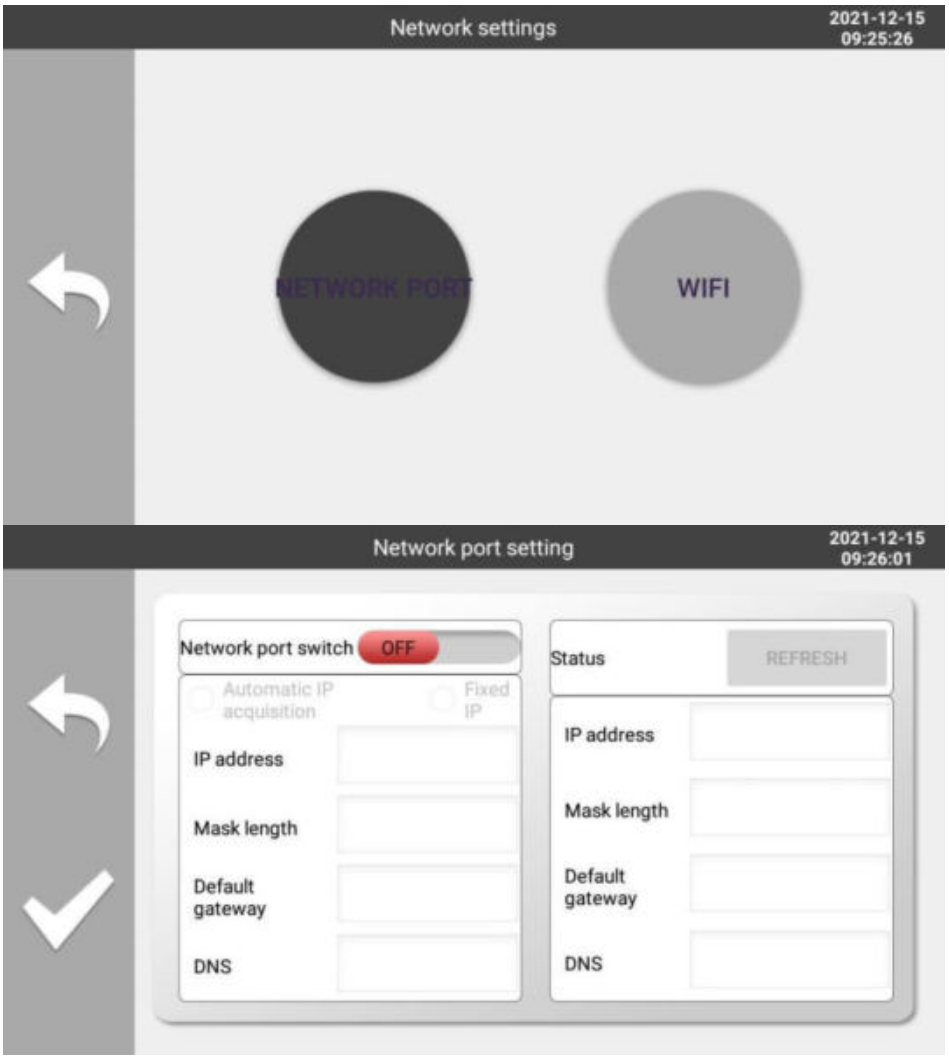


Figure 3.7-4 Network setting interface

Export logs

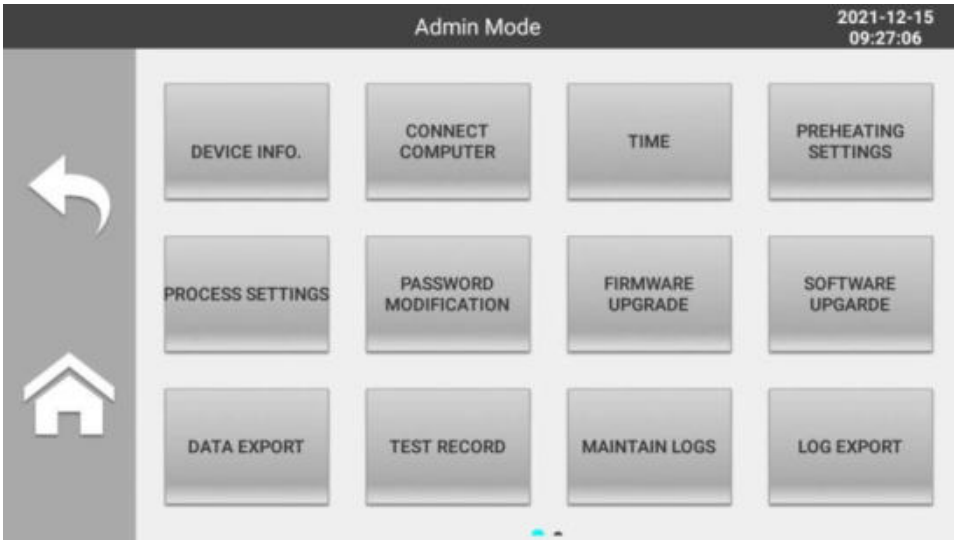
The instrument can record operating information every time it is turned on. The information will be stored in the internal memory of the instrument in the form of a log file. The user can export the data stored in the instrument through a USB storage device or a network port connection. Please click the "Export Logs" button in the setting interface, and you can select the log export method through the "USB DISK" or "ONLINE" button, as shown in Figure 3.7-5.

Figure 3.7-5 Log export interface

Administrator Mode

If you want to enable the administrator mode, you can log in by selecting the engineer account in the login interface and enter the password to enable. Please click the "administrator mode" button in the setting interface to enter the administrator mode. In the administrator mode, engineers can maintain the instrument and set the bottom system, as shown in figure 3.7-2.

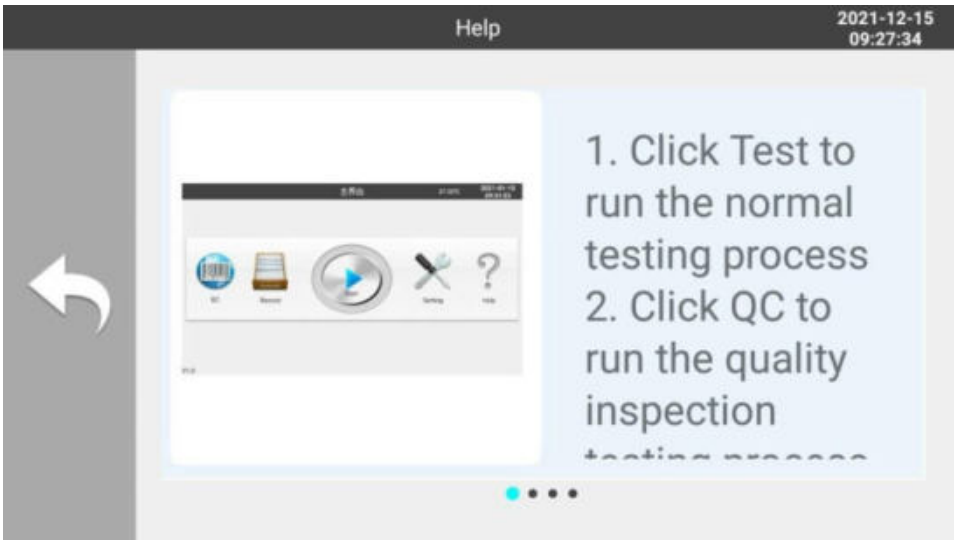
Note: Ordinary users cannot enable administrator mode



3.7-6 Administrator mode interface

3.8 Help

Click the "Help" button in the main interface to view the operation method of the instrument, as shown in figure 3.8-1.



3.8-1 Help interface

Note: The software interface is for reference only, subject to the actual display situation.

4. Maintenance

4.1 Daily Maintenance

Temperature Control Device Detection

Before starting work every day, after 30 minutes of preheating, touch the tray rack with your hand to feel whether there is obvious temperature rise. If so, it indicates that the temperature control device is running normally, and the test can be carried out normally. If not, the temperature control device may be damaged. Please contact the after-sales service agency or agent of Pushkang in time.

Cleaning Tray Rack

At the end of the work each day, clean the residue on the tray rack with a wet alcohol cotton.

Waste Disposal

After the test, the waste materials such as reagent disk and pipette tips should be cleaned up in time.

Note: during daily maintenance, please wear rubber gloves, wash hands with disinfectant after maintenance, and dispose reagent disk and pipette tips according to relevant regulations of medical waste.

4.2 Monthly Maintenance

Shell Cleaning

Wipe the surface of instrument shell with clean cloth dipped in purified water to remove dust and dirt. It is forbidden to use alcohol, gasoline and other flammable organic solvents to wipe the surface of the instrument, so as not to cause danger. When wiping, do not place the water container around the instrument to avoid the liquid flowing into the instrument. To avoid moisture, after the shell surface is dry, then turn on the power supply to use the instrument

Touch Screen Cleaning

Use a hairless soft cloth dipped in glass cleaning solution for wiping. Do not spray the cleaning solution directly on the surface of the touch screen. Do not use alcohol, gasoline and other flammable organic solvents to wipe the surface of the instrument to avoid danger.

4.3 Six Months or Annual of Maintenance

In order to keep MS100 working normally, the following maintenance is required:

- Add lubricating oil to the moving parts of the instrument.
- Wipe and maintain the optical components and mirrors.

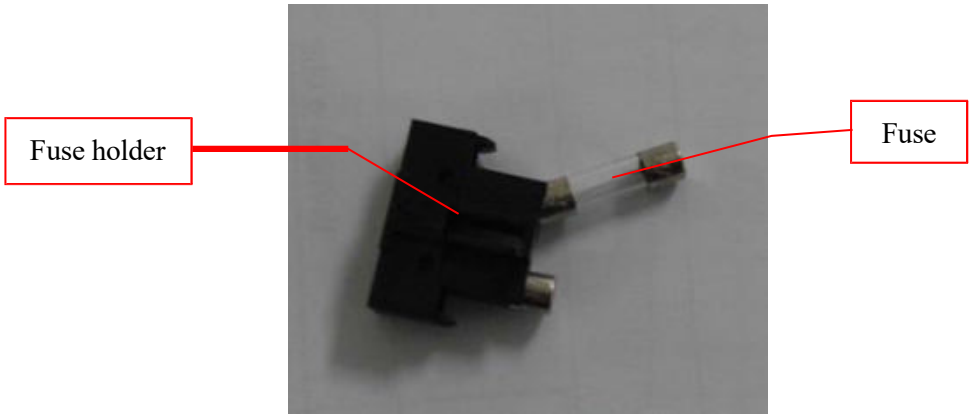
4.4 Replace the Fuse

Type of fuse: T1AL250V. The position of fuse holder is shown in Figure 4.4-1, and the replacement process is as follows:

Place the power switch in the "O" position and pull out the power connector of the power cord assembly. Use a tool (such as a screwdriver) to remove the fuse holder from the filter socket (in the direction of the arrow).

4.4-1 Power connector

The removed fuse holder is shown in figure 4.4-2. Remove the damaged fuse, replace the fuse of the same model, and re-install it on the filter socket. (the fuse holder is unidirectional insertion mode, please pay attention to the direction when installing it back to the original position of the filter socket!)



4.4-2 Fuse

5. Common Faults and Treatment Methods

This chapter lists the system fault and warning information, please deal with it in time according to the information. If the alarm status cannot be removed after taking measures, please contact the after-sales service agency or agent of Pushkang.

5.1 Common Faults and Treatment Methods

When the following faults occur, the user can take corresponding actions to solve the faults according to the description in the column of user handling measures. If it cannot be solved, please contact the after-sales service agency or agent of Pushkang in time.

No	Details	Measures
01	Light source fault	Restart the machine, if there is still a problem, please contact the manufacturer's after-sales service department
02	Motor fault	
03	Communication failure	
04	Instrument crash	
05	Quality control lose control	Repeat the test. If there are still problems, please contact the manufacturer's after-sales service department
In case of other faults, please contact the after-sales service agency or agent of Pushkang in time!		

5.2 Common Error and Handling Methods

When the following errors appear, the user can take corresponding actions to solve it according to the description in the column of processing method. If it cannot be solved, please contact the after-sales service agency or agent of Pushkang in time.

No	Error warning	Treatment Methods
1	Number input cannot be empty	The patient number must be entered
2	Open the cover, the test is invalid, please take back the test object	Do not open the cover during the test
3	Device USB disk not detected	Insert U disk before exporting log

6. After-sales Service

6.1 Warranty Period

The packaged instrument shall be guaranteed within 12 months from the date of installation under the condition of complying with the rules of transportation, storage and use. (Start from the record date of the product warranty card when the instrument is installed.)

Content of the Warranty

If the instrument fails to operate normally according to the instruction manual due to product quality problems, the company is responsible for repairing the instrument, replacing parts or products for users within the warranty period free of charge.

Non Warranty Items

Even within the warranty period, if the faults of the instrument belong to the following contents, the company will carry out paid repair:

- Failure and damage caused by failure to use according to the method recorded in
- the instruction manual;
- Failure to use in accordance with the method recorded in the operation manual, resulting in failure and damage;
- Failure and damage caused by fire, earthquake and other force majeure;
- Failure and damage caused by using non specified power supply (voltage, frequency) or abnormal voltage;
- Failure caused by repair, adjustment and modification not carried out by our company or designated after-sales service organization.

Note: consumable goods indicated in the instruction manual are not covered by the warranty. Maintenance beyond the warranty period is paid service.

6.2 Production Date and Service Life

Production date: See the label.

Service life: the service life specified in the operation manual refers to 5 years after the implementation of regular maintenance, replacement of consumables, repair of components and necessary overhaul.

6.3 After-Sales Service Company Information

Company name: Zhejiang Pushkang Biotechnology Co., Ltd
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