ANALIZZATORE PUSHKANG MS200

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 MS200 è un analizzatore di chimica clinica portatile con funzioni completamente automatizzate 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 MS200 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.

EASYPHARM S.R.L. - *Sede legale ed operativa:* Via degli Olmetti, 14/16/18 int 25 – 00060 Formello (RM) – Tel. 06.9075226 – 06.90409154 - 06.31056284 – Fax 06.92912957 — Nsis 008703 - www.easypharm.it - info@easypharm.it

- Deposito preliminare: Località Monte Moro – Area P.I.P. – 02024 Pescorocchiano (RI) – Tel. 0746.396773 – Nsis 011909

PUSHKANG®

MS200
Analizzatore Chimico Automatico

Centrifugal microfluidic biochemical POCT test platform

- Diluizione e dosaggio automatico del diluente
- Scelta tra numerose combinazioni di reagenti per analisi cliniche complete
- Strumento di dimensioni compatte con ampio 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
Test time	12 min
Code identification	Riconoscimento automatico del disco reagenti tramite QR code
Temperatura di reazione	37±0.5℃

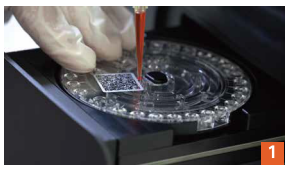
Connessione	USB, LAN, ,
Stampante	Stampante termica incorporata
Sistema operativo	Android, supporto LIS system
Memoria interna	4GB
Supply voltage	AC100V-240V，50-60HZ
Dimensioni	210mm*250mm*310mm
Peso	10KG

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 Ca2+ PHOS CO2
Electrolyte 7	K+ Ca2+ Na+ Cl- CO2 Mg2+ 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*

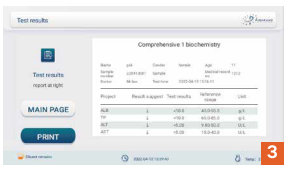
**Calculated / GSP# means coming soon*

Istruzioni d'uso



Aggiungere campione

Premere "start"



Risultato test

DISTRIBUTORE ESCLUSIVO IN ITALIA

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:	Automated Chemistry Analyzer (MS200) General Chemistry 9 Test Panel General Chemistry 13 Test Panel Emergency Room 13 Test Panel Electrolyte 7 Test Panel 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.

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

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.

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

DECLARATION OF CONFORMITY

ACCORDING TO In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746

EU Representative

SUNGO Cert Gmbh
Harffstr. 47,40591 Düsseldorf, Germany
SRN: DE-AR-000010869

Device Classification

Classification: Class A.

Rule: According to Rule 5, Annex VIII, of In Vitro Diagnostic Medical Devices Regulation (EU)2017/746.

Applicable Standards

EN ISO 20417: 2021,
EN ISO 15223-1:2021,
EN ISO 18113-1:2011,
EN ISO 14971:2019,
EN ISO 18113-3:2011

Remark

The declaration of conformity is valid in connection with the release technical document CE/IVDR-24. All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: 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.

Product Information

Name: Automated Chemistry Analyzer
Model: MS200
Basic UDI-DI: /
Classification: Class A

Conformity Assessment

Compliance of the designated product with the In Vitro Diagnostic Medical Devices Regulation (EU)2017/746 has been assessed by issuing the EU declaration of conformity referred to in Article 17 after drawing up the technical documentation set out in Annexes II and III.

Declaration

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 and the applicable standards above.

Signature: Date: 2022.03.28

Position: GM Place: Shaoxing /China

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00188079

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA20**		
	Bezeichnung / Name **Bezirksregierung Düsseldorf, Dezernat 24**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40474**
	Straße, Haus-Nr. / Street, house no. **Cecilienallee 2**		
	Telefon / Phone **+49-211-4750**		Telefax / Fax **+49-211-4752671**
	E-Mail / E-mail **dez24.mpg@brd.nrw.de**		

Anzeige / Notification

	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **14.10.2022**		Registriernummer / Registration number **DE/CA20/00115311**

Rechtsgrundlage / legal basis

☐ In-Vitro-Diagnostika (98/79/EG) / German Medical Device Act (98/79/EG)

☐ Artikel 110(3) Verordnung (EU) 2017/746 (Legacy Device) / Article 110(3) Regulation (EU) 2017/746 (Legacy Device)

☒ Verordnung (EU) 2017/746 (IVDR) / Regulation (EU) 2017/746 (IVDR)

Typ der Anzeige / Notification type

☒ Erstanzeige / Initial notification

☐ Änderungsanzeige / Notification of change

☐ Widerrufsanzeige / Notification of withdrawal

Frühere Registriernummer bei Änderungs- und Widerrufsanzeige
Previous registration number if notification has been changed or withdrawn

Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG

☐ Hersteller / Manufacturer

☒ Bevollmächtigter / Authorised Representative

☐ Einführer / Importer

☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG / Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG

☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV
Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV

☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG
Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG

Anzeigender / Reporting organisation (person)

	Code **DE/0000048299**		
	Bezeichnung / Name **Sungo Cert GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40591**
	Straße, Haus-Nr. / Street, house no. **Harffstr. 47,**		
	Telefon / Phone **+49-211-97634133**		Telefax / Fax
	E-Mail / E-mail **sungo.group@yahoo.com**		

Hersteller / Manufacturer

	Bezeichnung / Name **Zhejiang PushKang Biotechnology Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **C408, Science and Technology Innovation Park**		Postleitzahl / Postal code **312366**
	Straße, Haus-Nr. / Street, house no. **NO.398, Mahuan Road, Binhai new Area, 312366 Shaoxing, Zhejiang**		
	Telefon / Phone **+86-575-82002091**		Telefax / Fax
	E-Mail / E-mail		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9)
Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG

	Bezeichnung / Name **Ninggang Luo**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40591**
	Straße, Haus-Nr. / Street, house no. **Harffstr. 47,**		
	Telefon / Phone **+49-211-97634133**		Telefax / Fax
	E-Mail / E-mail **sungo.group@yahoo.com**		

Vertreter / Deputy (optional)

	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	☐ Erstanzeige / Initial notification ☒ Änderungsanzeige / Notification of change		

In-vitro-Diagnostikum / In vitro diagnostic medical device	
	Klassifizierung / Classification ☒ Klasse A / Class A ☐ Klasse A - steril / Class A - steril ☐ Klasse B / Class B ☐ Klasse C / Class C ☐ Klasse D / Class D
	App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no
	Anzeige nach § 25 Abs. 3 Nummer 3 MPG Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG ☐ "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"
	Handelsname des Produktes / Trade name of the device **Automated Chemistry Analyzer**
	Produktbezeichnung / Name of device
	Angabe der benutzten Nomenklatur / Nomenclature used ☒ EDMS-Klassifikation / EDMS Classification ☐ GMDN
	Nomenklaturcode / Nomenclature code
	Nomenklaturbezeichnung / Nomenclature term
	Kurzbeschreibung / Short description In Deutsch / In German **Sie wird in Verbindung mit Chemikalien, die von unserer Firma hergestellt werden, zur Quantifizierung von Analysestoffen in menschlichen Proben verwendet. Dieses Gerät eignet sich für Labore mit speziellen Prüffunktionen in medizinischen Einrichtungen, wie z. B. in einem zentralen Labor, einem ambulanten Labor, einem klinischen Labor, einem medizinischen Zentrum usw. Wird nur für die Diagnose außerhalb des Körpers verwendet.**
	In Englisch / In English **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.**

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices	
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	☐ In übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A) In conformity with Common Technical Specifications (for Annex II List A devices)
	Ergebnisse der Leistungsbewertung Outcome of performance evaluation

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Düsseldorf**

Datum
Date **2022-10-14**

Name
Frank Xu

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible		Telefon / Phone

CE

Automated Chemistry Analyzer
Instruction for Use
(Type: MS200)

Zhejiang PushKang Biotechnology Co.,Ltd.

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Preface

1. Description

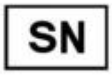
Thank you for purchasing the MS200 Automated Chemistry Analyzer ! Read all product manuals and consult with Pushkang trained personnel before you operate the system. Do not perform any procedure before you carefully read all instructions. Always follow the product labels and the recommendation from the manufacturer. For more information, contact Pushkang.

2. Basic Information

- Product name: Automated Chemistry Analyzer
- Specifications and models: MS200
- Size: 310mm×250mm×210mm
- Weight: 10 kg
- 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; 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
	USB connector
	LAN network connector
	Fragile, handle with care
	This way up
	Keep away from rain
	Stacking limit by number

【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: MS200 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.

【Instrument Operation Instructions】

- Install and operate instruments according to instructions, the instrument model applicable to this manual is: MS200.
- 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.
- If the instrument is stopped for maintenance or treatment, dry gauze should be used to wipe the residual liquid from various parts of the instrument to ensure that the instrument is dry for diluent empting, instrument cleaning and disinfection. It is necessary to reliably fix the moving parts such as the warehouse door.

1 Summary of Instrument

Thank you for choosing the MS200 Automated 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 Operating Principle

Automated 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.

1.2 Working Conditions and performance

1.2.1 Working Conditions:

a) Power voltage: ~220V-240V, 50/60Hz;

b) Rated power: 180VA;

c) Environment temperature: 15℃~30℃;

d) Relative humidity: 40%~70%;

e) Atmospheric pressure: 85.0kPa~106.0kPa;

f) Stay away from interference source of strong electromagnetic field;

g) Avoid direct exposure to strong light;

h) Well-ventilated environment;

i) With good grounding;

1.2.2 Performance

1.2.2.1 Stray light

The absorbance is not less than 2.3.

1.2.2.2 Absorbance linearity

The maximum absorbance within ±5% relative bias shall not be less than 2.0.

1.2.2.3 Accuracy of absorbance

Should meet the requirements in the following table 1.2-1.

Table 1.2-1 requirements of accuracy of absorbance

Absorbance	Allowable error
0.5	±0.025
1.0	±0.07

1.2.2.4 Stability of absorbance

The change in absorbance should not be greater than 0.01.

1.2.2.5 Repeatability of absorbance

Expressed by the coefficient of variation, it should not be greater than 1.5%.

1.2.2.6 Temperature accuracy and fluctuation

The temperature value is within ±0.3℃ of the set value, and the fluctuation is not more than ±0.2℃.

1.2.2.7 Adding sample accuracy and repeatability

The accuracy of adding sample should not more than ±5% and the coefficient of variation should not more than 2% when testing 110μL rated adding sample amount of the instrument.

1.2.2.8 Intra-assay precision in clinical laboratories

The coefficient of variation (CV) should meet the requirements in the following table 1.2-2.

Table 1.2-2. Intra-assay precision requirements in clinical laboratories

Item	Concentration range	Coefficient of variation requirement/%
Alanine aminotransferase (ALT)	30U/L~50U/L	CV≤5
Urea (UREA)	7.0mmol/L~11.0mmol/L	CV≤2.5
Total protein (TP)	50.0g/L~70.0g/L	CV≤2.5

1.2.2.9 Appearance

The appearance should meet the following requirements:

a) The graphic symbols and words on the panel shall be accurate, clear and uniform;
b) The connection of fasteners shall be firm and reliable without looseness
c) The moving parts should be stable, and should not be stuck, jump and significant empty return. The key group should be flexible.

1.2.2.10 Main function

The instrument has the following main functions:

a) The instrument has a self-check function;

b) Prompt function: There should be corresponding prompts for replacement of light source components, abnormal absorbance, test completion or error;
c) Software function: should include quality control, record, setting, help, test interface;
d) User management: should include user identification methods and user types and permissions;
e) Communication function: The instrument should have 1 USB-A connector, 1 USB-B connector and 1 LAN interface; the instrument has WiFi connection function.

1.2.2.11 Safety Requirements

Should meet the requirements of EN61010-1: 2010+A1: 2019, EN 61010-2-101:2017.

1.2.2.12 Electromagnetic Compatibility

Should meet the requirements of EN 61326-1: 2013 and EN 61326-2-6:2013.

1.3 Software System

1.3.1 Software Edition Number

Name of the software: MS200 Automated chemistry analyzer software, software edition number: V1.0.

1.3.2 Operating Condition

1) Operating system: Android5.0 or above;
2) RAM: 1G;
3) Internal storage memory: 4G;
4) Monitor resolution: 1024×600;
5) Lower computer system: dsPIC33;
6) Random access memory: 1M.

1.3.3 Data Interface

USB connector, LAN port.

1.3.4 User Access Control

User identification method: User name, password

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

1.4 Sample Type

Whole blood, plasma, serum.

1.5 Applicable Reagents

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

1.6 Transportation and Storage Requirements

【Transportation Requirement】

The packed MS200 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 not more than 70%, no corrosive gas.

1.7 Product Structure

MS200 chemistry analyzer is composed of detector, attemperator, DC motor, power supply, touch screen and printer.

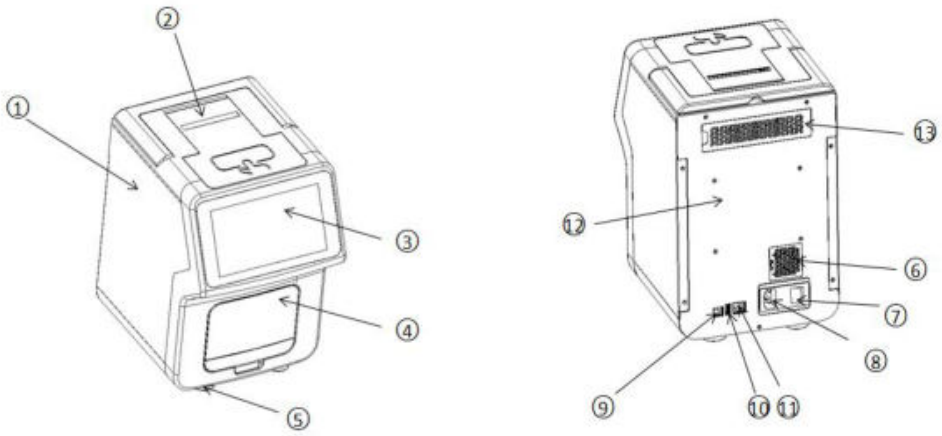


Figure 1.7-1 Integral structure

1.main body cover 2.printer 3. Touch screen 4. Bin gate 5. Foundation
6. Air inlet 7.Power switch 8. Power socket 9.USB (B) port 10. USB (A) port
11. LAN port 12.Rear panel 13.Air outlet

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 2.2-1.

Table 2.2-1 Packing list

Material name	Quantity
Automated Chemistry Analyzer	1
Power line	1
Thermal printing paper	1
Diluent bottle	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%~70%;
- 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 20kg.

2.3.3 Power Requirement

- Power voltage: ~220V-240V;
- Rated frequency: 50/60Hz;
- Rated power: 180VA;
- 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 20kg.

2.4.2 Computer Connection

If you need to connect the computer, use the communication cable to directly connect the USB-B.

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.

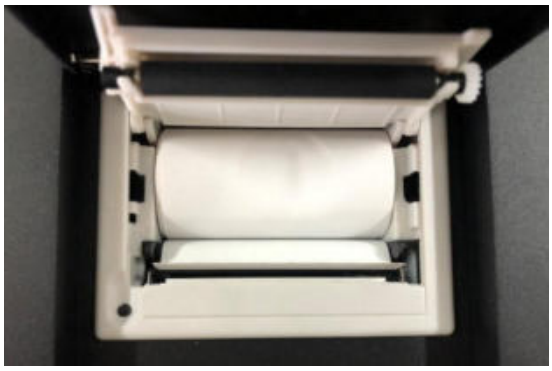
2.4.4 Installation of Thermal Printing Paper

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:

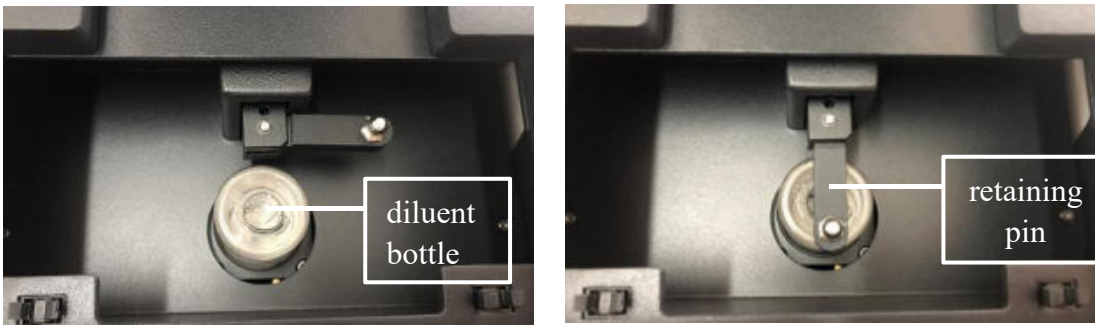


2.4-1 Printing paper installation diagram

2.4.5 Installation of diluent bottle

Gently press to open the top cover of the instrument, locate the position of the diluent bottle, push the retaining pin to the right, take out the empty diluent bottle, put the new diluent bottle with the nozzle facing down, and push the retaining pin to the left to secure the diluent bottle, as shown in Figure 2.4-2.

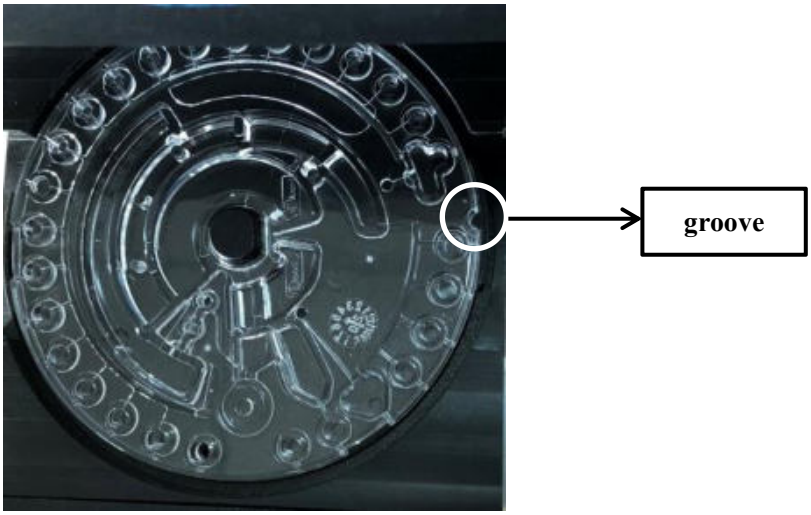
Note: Before loading the new diluent, please put the nozzle down and press the diluent bottle for 5~7 times until the nozzle water is normal before installation.



2.4-2 Diluent bottle 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.



2.4-3 Diagram of reagent disk installation

3 Operating Instructions

3.1 Pre-startup Inspection

- Make sure the power cord is properly connected.
- Confirm thermal printing paper allowance.
- Confirm diluent allowance.

3.2 Start-up System

After correctly connecting the power cord, turn on the power switch on the back of the instrument. After the instrument is turned on, it automatically 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.

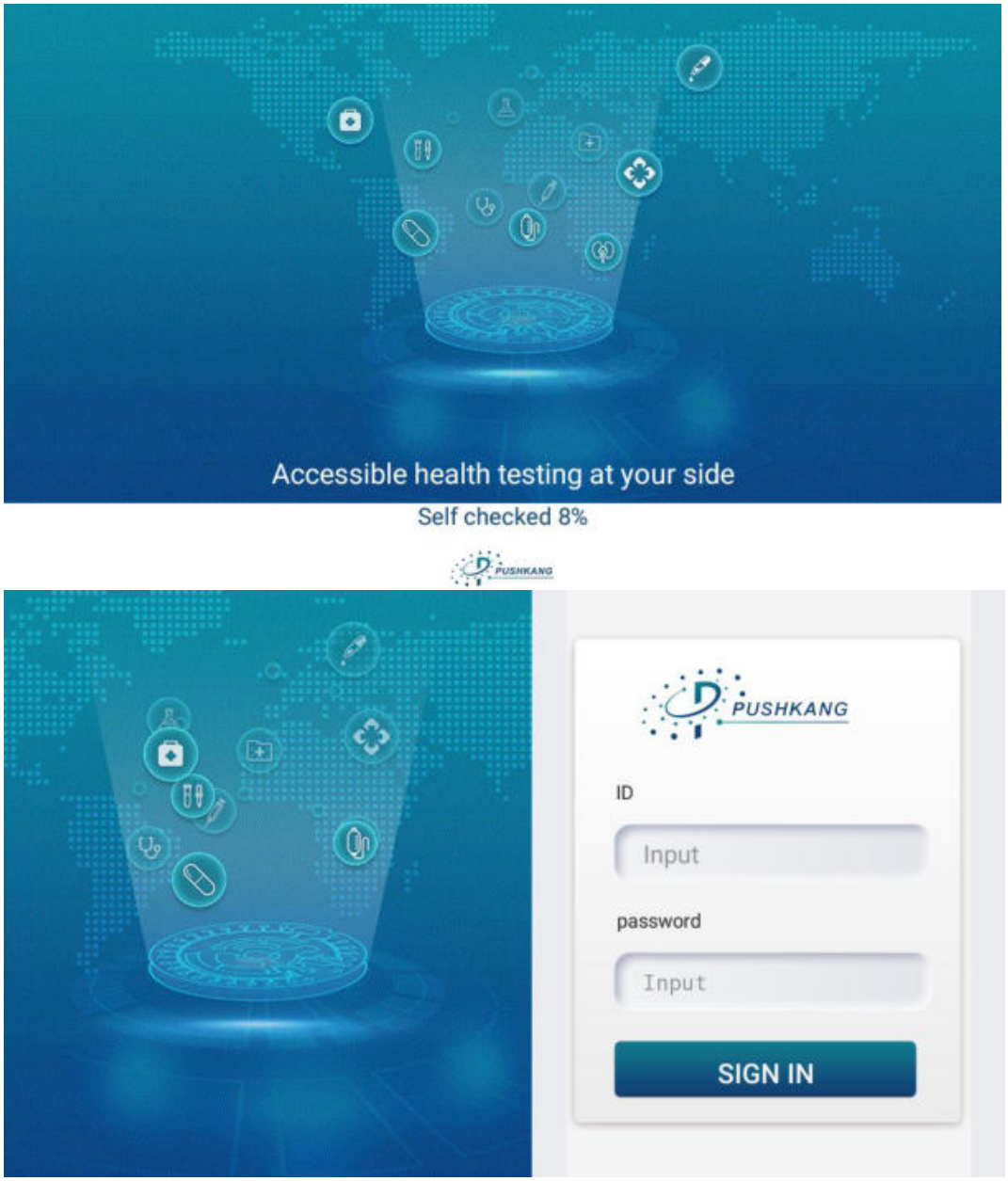


Figure 3.2-1 Instrument self-check and login interface

3.3 Main Interface

On the upper right of the main interface is the “in/out” button, and on the lower side are the diluent allowance, time and real-time temperature from left to right, and the middle part is the function area, which includes four parts: “Start”, “Record”, “Set” 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, as shown in figure 3.4-1.

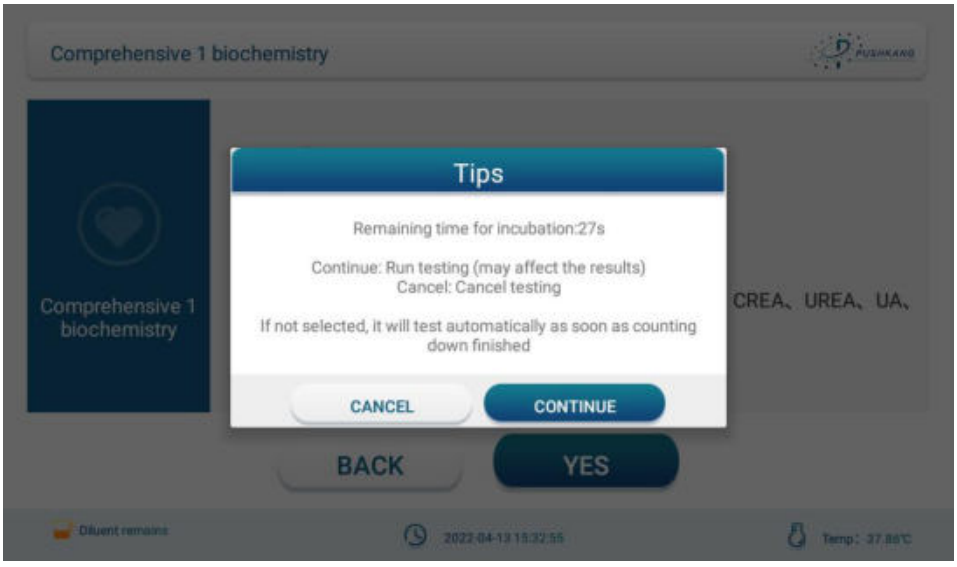


Figure 3.4-1 incubation prompt

Note: Do not start the test before the incubation is stable, so as not to affect the test results.

3.4.1 Normal Test

After preheating, in the main interface, click on the “start” button, the interface will display “please put in the disk” prompt, as shown in figure 3.4-2 shows, take out the reagent disk from aluminum sealing bag, place in a horizontal table, use the micropipettor or other for sample adding equipment, inject the sample into the reagent disk through the "Sample"

sampling hole; please refer to the reagent manual for the sample amount. After placing the disk in the correct position, click OK, and the instrument will automatically scan the QR code on the disk.

Figure 3.4-2 Please put in the disk prompt

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.

After scanning, the system will automatically read the reagent disk information, as shown in figure 3.4-3.Please confirm the test item, if it is correct, please click the “Yes” button, if it is wrong, please click “back” button. After confirmation, the system will automatically add diluent for ten times.

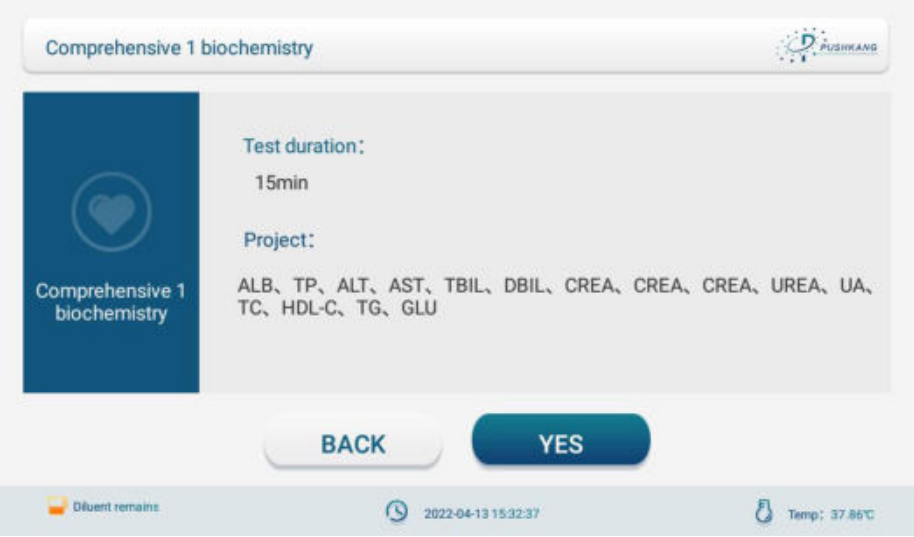


Figure 3.4-3 Test item determination interface

After the diluent is added, the instrument starts testing, and the software enters the sample information input interface, as shown in Figure 3.4-4, enter the name, sample number, medical record number, gender, age, and testing doctor in sequence.

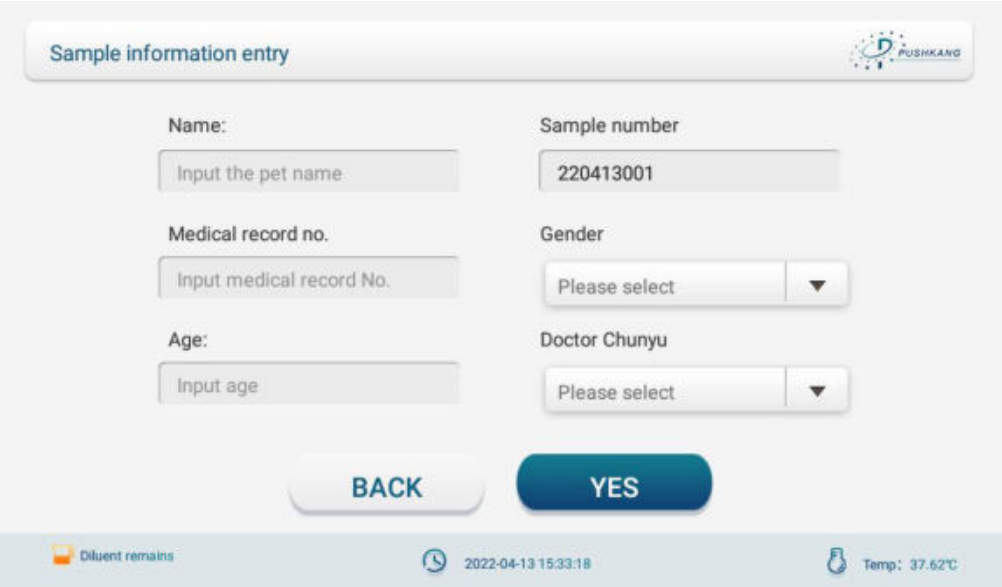
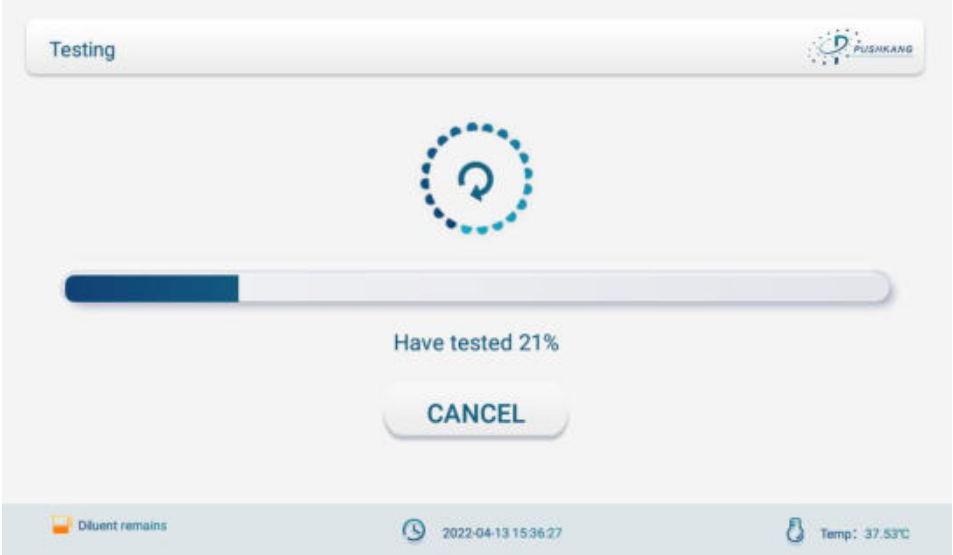


Figure 3.4-4 Sample information input interface

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



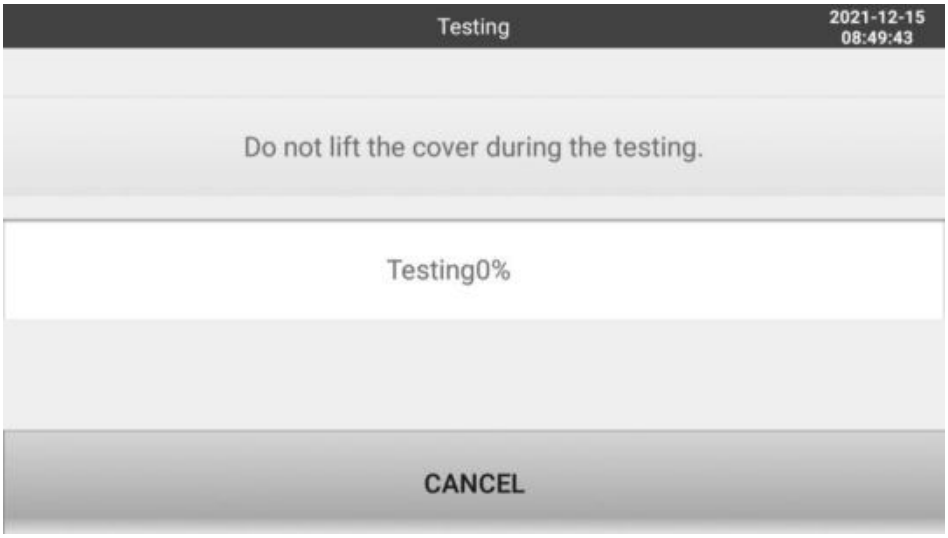


Figure 3.4-5 Testing process interface

After the test is completed, the test results will be displayed, as shown in figure 3.4-6, 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.

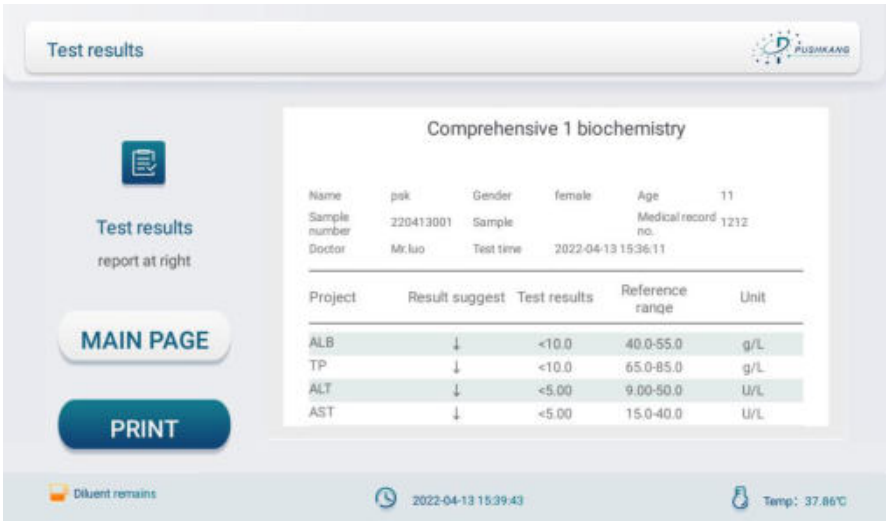


Figure 3.4-6 Test result interface

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 the detection, as shown in figure 3.4-7. 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.

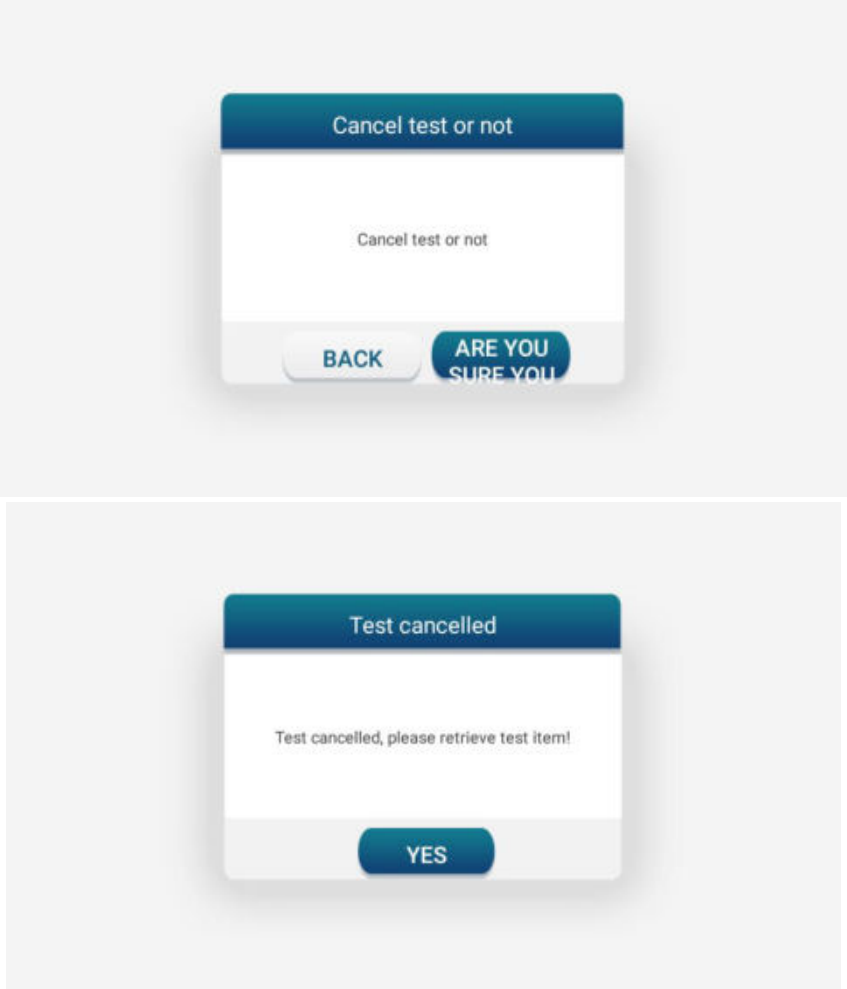


Figure 3.4-7 Whether to cancel the detection interface

3.5 Maintenance

In the main interface, click the “maintenance” button to enter maintenance interface.

3.5.1 Quality Control

If it is necessary to conduct quality control, you can 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. Click the "Quality control" button on the maintenance interface, put the disk in , the instrument will automatically scan the QR code on the dish and prompt whether to carry out the quality control test. After confirmation, the quality control test will be carried out directly, as shown in Figure 3.5-2.

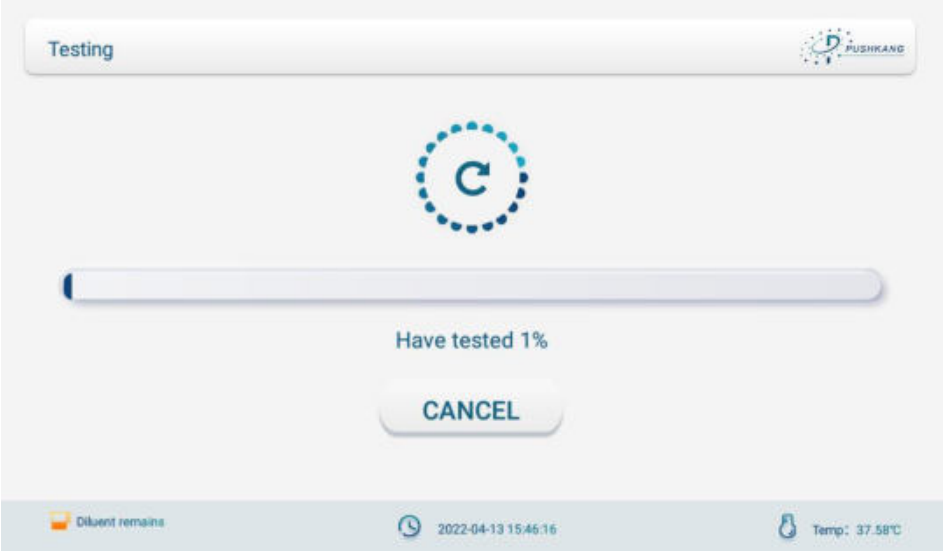


Figure 3.5-2 Quality control test interface

3.5.2 Setting

Click the “Settings” button to enter the settings interface, where you can view “Device info.”, “Brightness”, “Network settings” , “Printer settings” , “Export logs”, “items reference range settings” , as shown in figure 3.5-3.

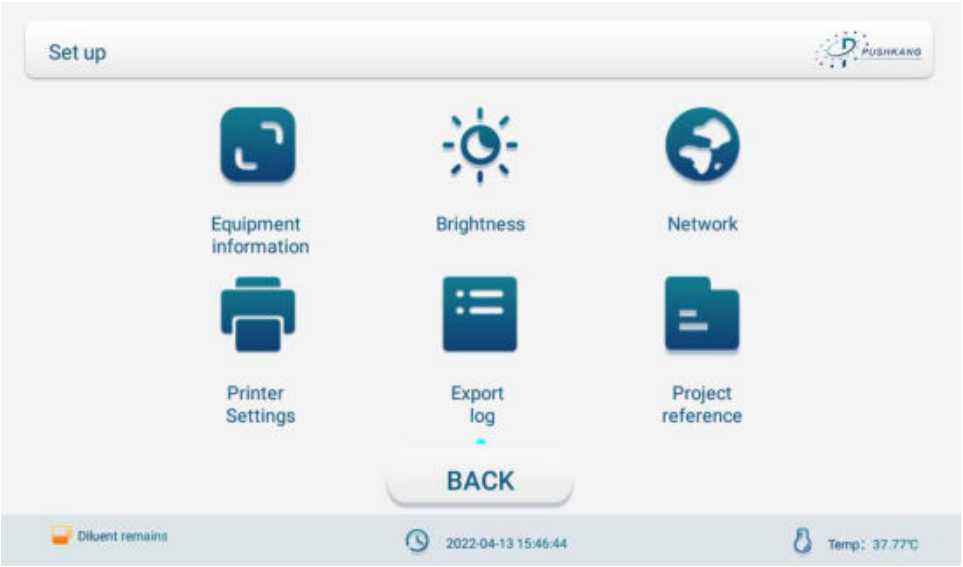


Figure 3.5-3 Setting interface

3.5.2.1 View Device Information

Click the "Device info." button in the setting interface to enter the device information interface to view the device information, as shown in figure 3.5-4.

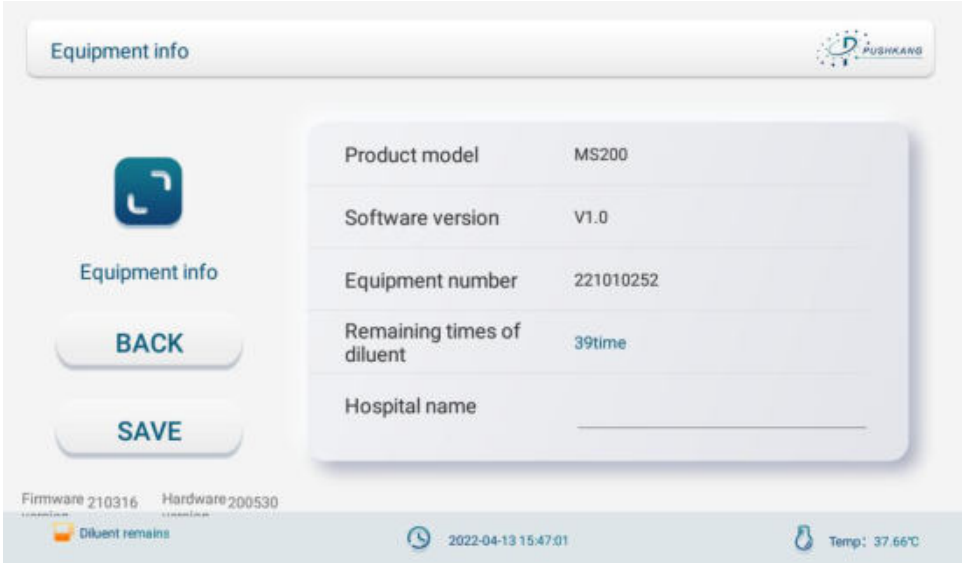


Figure 3.5-4 Device Information Interface

3.5.2.2 Adjust Brightness

Click the "Brightness" button in the setting interface to enter the screen brightness adjustment interface to adjust the screen brightness, as shown in figure 3.5-5.

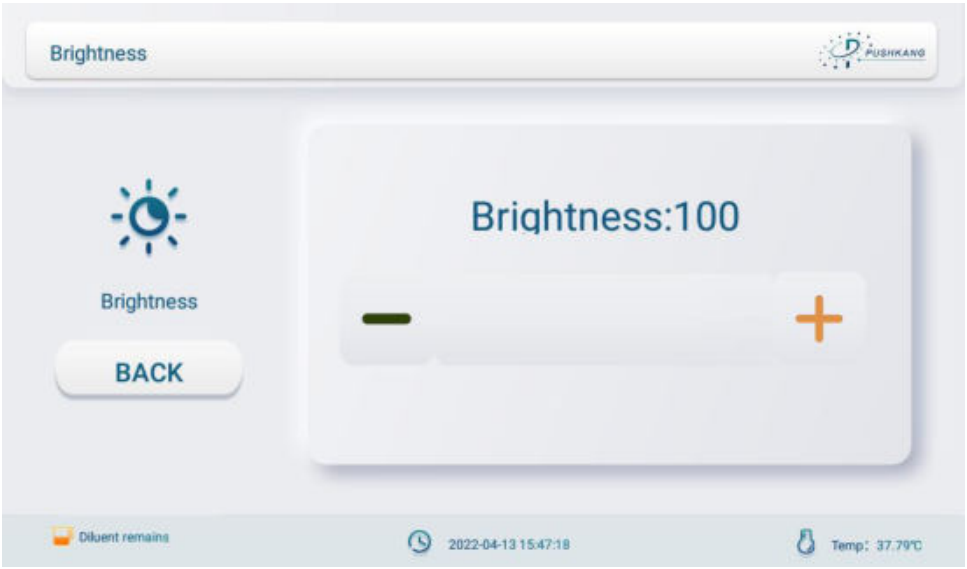


Figure 3.5-5 Brightness adjustment interface

3.5.2.3 Network Settings

The instrument can click the "Network Settings" button on the setting interface to perform network, WIFI, LIS information settings, as shown in figure 3.5-6.

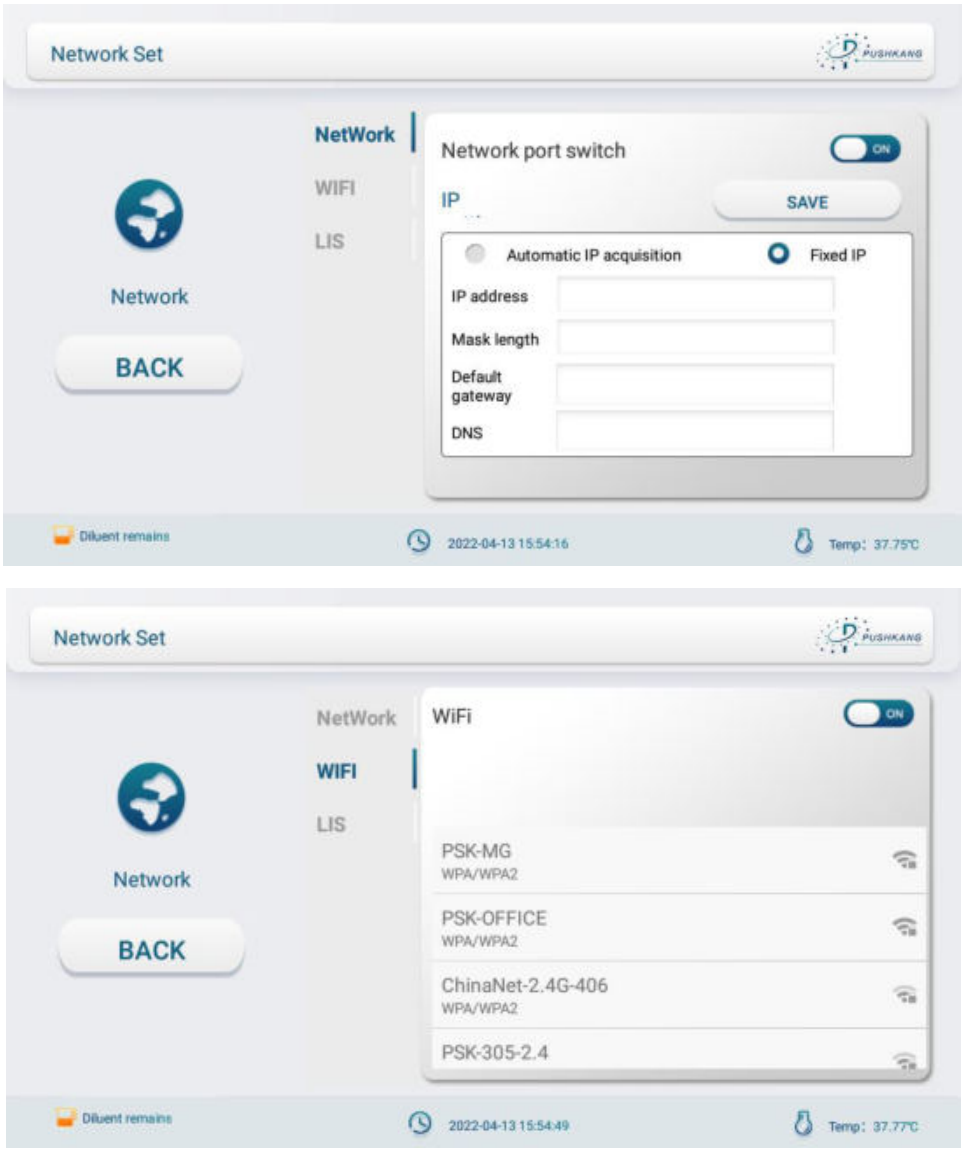


Figure 3.5-6 Network setting interface

3.5.2.4 Printer settings

This instrument has two options: automatic printing and manual printing. Click the corresponding option to set the report printing mode after the completion of the instrument test, as shown in Figure 3.5-7.

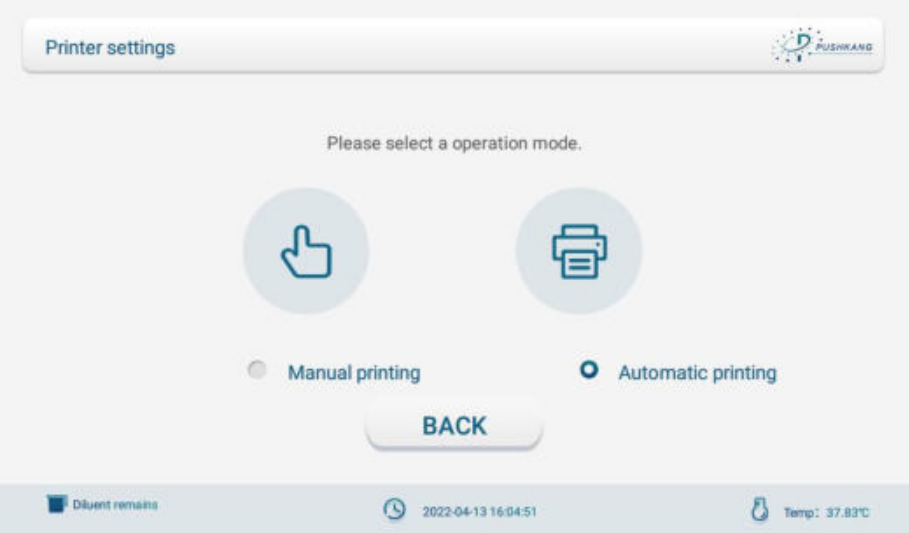


Figure 3.5-7 Printer setting interface

3.5.2.5 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 3.5-8.

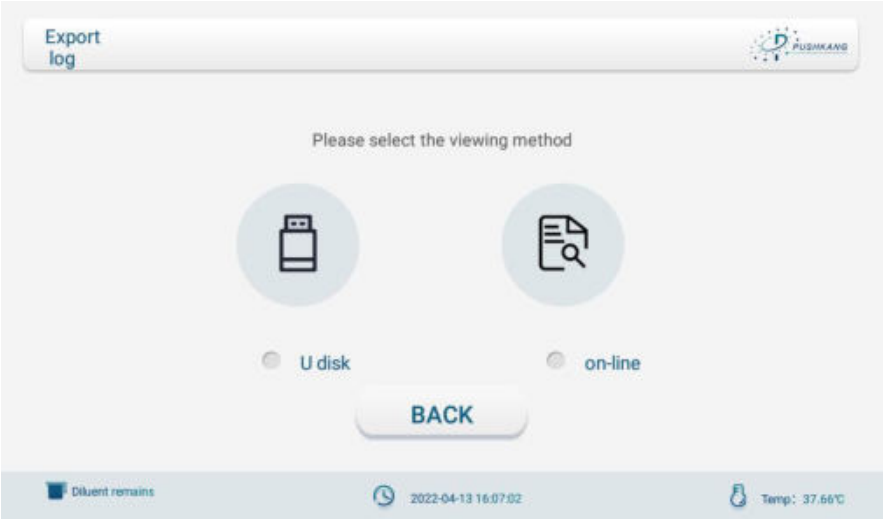


Figure 3.5-8 Log export interface

3.5.2.6 Items reference range settings

The instrument can click the “ Items reference range” button on the setting interface to enter items reference range settings interface, click the corresponding test item to set the reference range of the item, as shown in figure 3.5-9.

Figure 3.5-9 Items reference range settings interface

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 record” and “Test record” can be selected according to the requests.

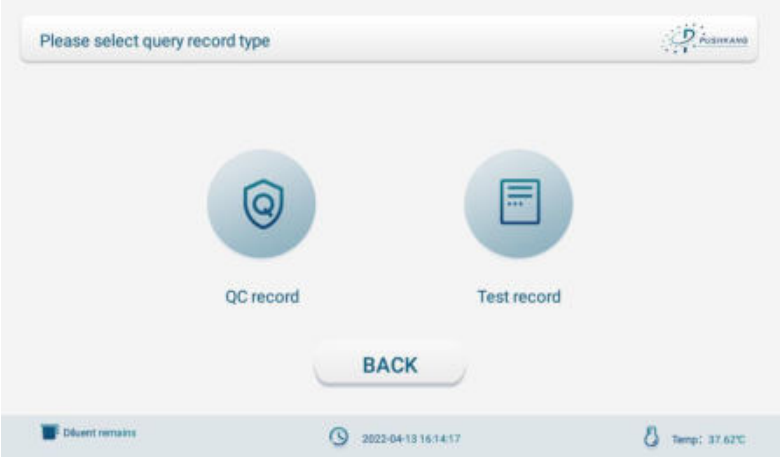


Figure 3.6-1 Record interface

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.

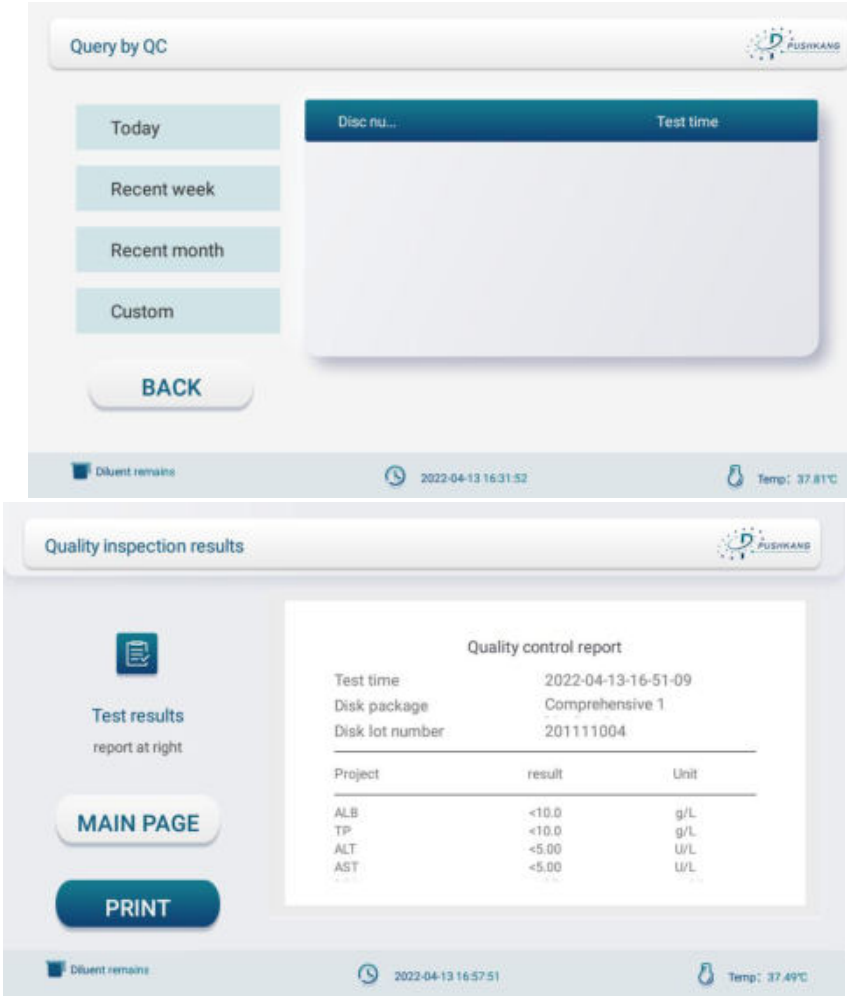
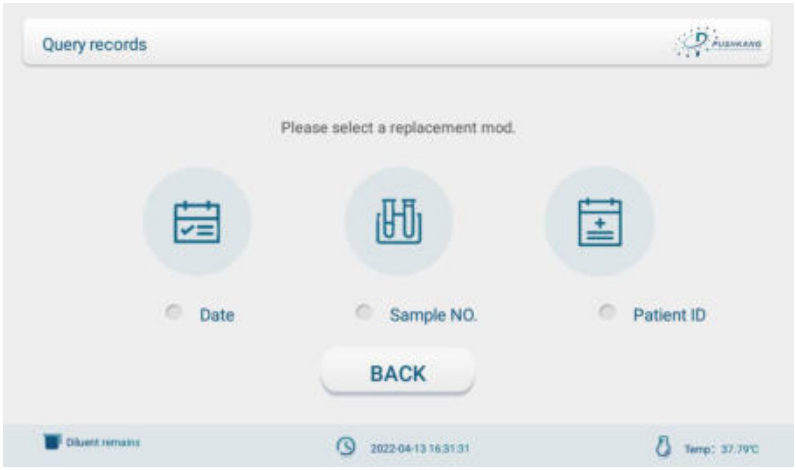
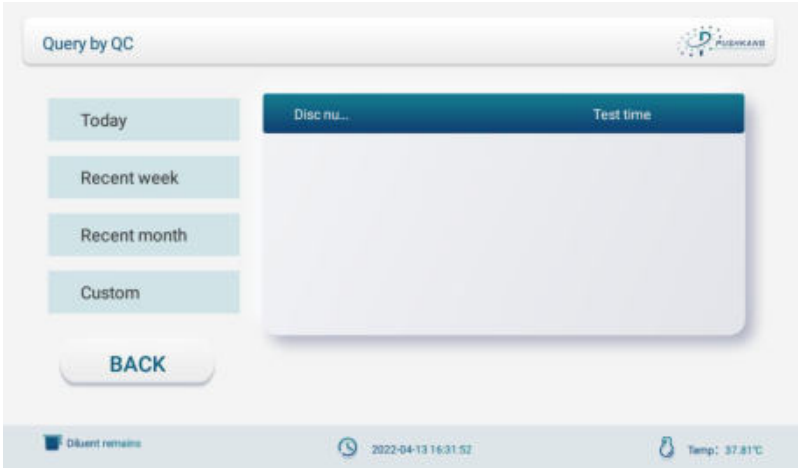


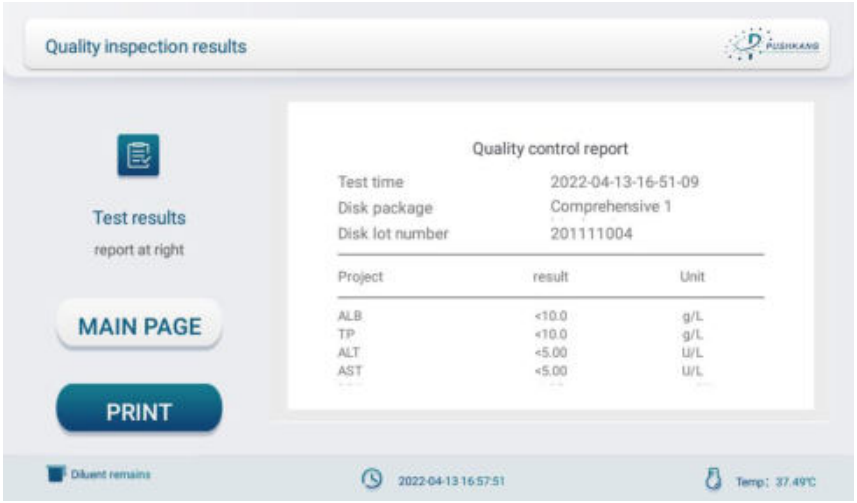
Figure 3.6-2 Quality control query interface

3.6.2 Test record

Click the “Test record” button on the record interface to enter the test result query interface. You can query by date, sample number and medical record number. You can query the result interface within the corresponding information, select the result you want to view and click to view the test result, as shown in Figure 3.6-3.


Query records
Please select a replacement mod.
Date
Sample NO.
Patient ID
BACK


Query by QC
Today
Recent week
Recent month
Custom
BACK
Disc nu...
Test time


Quality inspection results
Test results
report at right
MAIN PAGE
PRINT
Quality control report
Test time 2022-04-13-16-51-09
Disk package Comprehensive 1
Disk lot number 201111004
Project result Unit
ALB <10.0 g/L
TP <10.0 g/L
ALT <5.00 U/L
AST <5.00 U/L

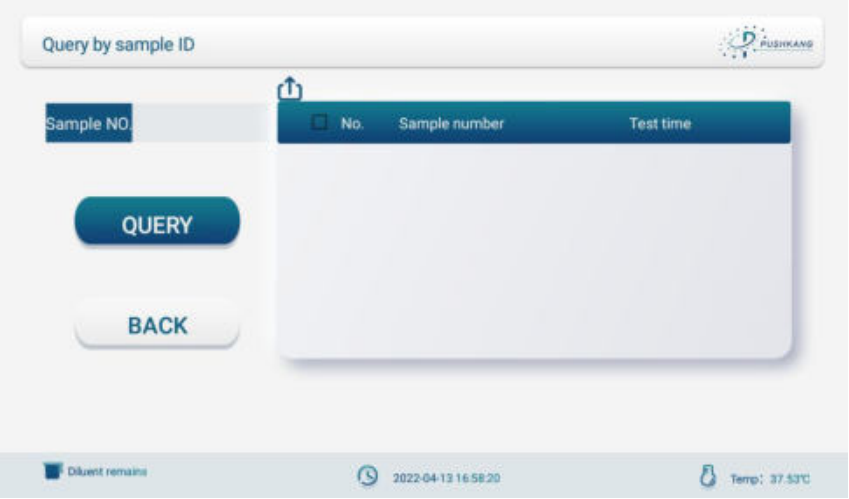


Figure 3.6-3 Test record query interface

3.7 Help

Click the “Help” button in the main interface to view the operation method of the instrument, as shown in figure 3.7-1.

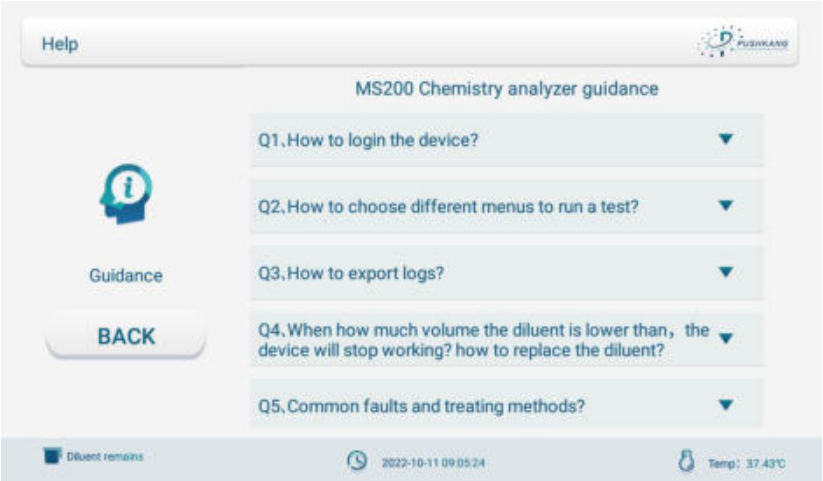


Figure 3.7-1 Help interface

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

4 Maintenance

4.1 Daily Maintenance

4.1.1 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.

4.1.2 Cleaning Tray Rack

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

4.1.3 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

4.2.1 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

4.2.2 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 MS200 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).

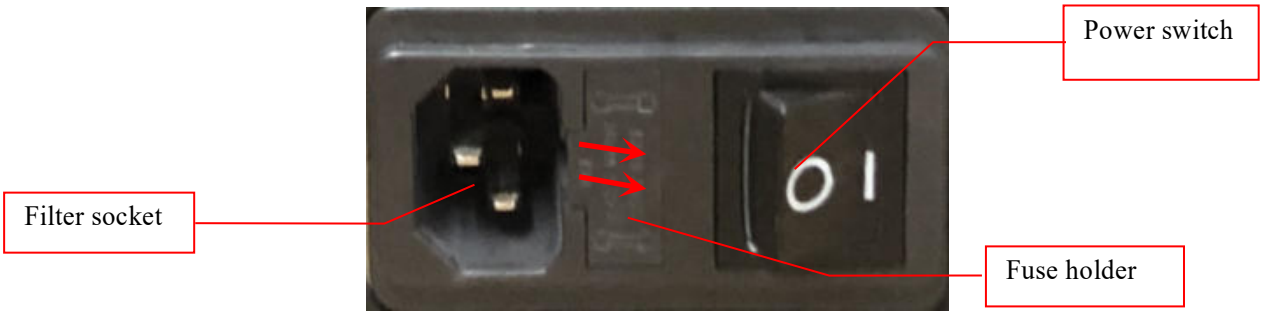


Figure 4.4-1 Power connector

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!)

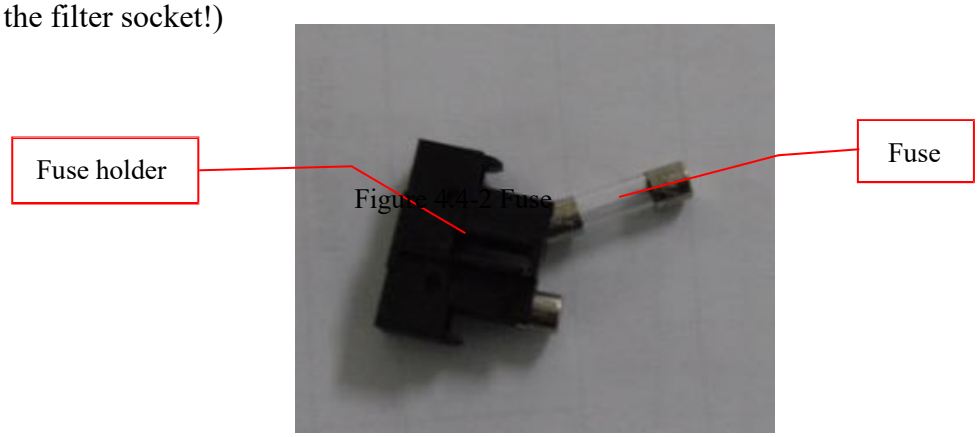


Figure 4.4-2 Fuse

5 Electromagnetic Compatibility and Noise

- Do not place this instrument next to equipment that produces a high level of electrical noise.
- Electromagnetic waves may be generated during use of the instrument. Do not use instruments sensitive to electromagnetic waves near the instrument.
- The instrument meets the emission and immunity requirements specified in EN 61326-1:2013 and EN 61326-2-6:2013, as shown in the table below.
- The user is responsible for ensuring the electromagnetic compatibility 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 this equipment near strong radiation sources (such as unshielded radio frequency sources), otherwise it may interfere with the normal operation of the equipment.

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

Table 4 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 5 Electromagnetic compatibility 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

6 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.

6.1 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	Insufficient sample	Perform the test again
06	Insufficient diluent	
07	Insufficient mixed liquor	
08	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!		

6.2 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.

SN	Error code	Error type	Treatment Methods
1	0x10006	Communication error	Restart
2	0x40001	Self-check temperature error	Self-inspection again
3	0x50001	Self-inspection motor error	Self-inspection again
4	0x60001	Self-inspection data is incorrect	Self-inspection again

5	0x81001	Quality control panel does not exist	Check the panel
6	0x81002	Quality control sample is unqualified	Check the sample
7	0x81003	Quality control diluent is unqualified	Check the diluent
8	0x81004	Quality control mixed liquor is unqualified	Check the mixed liquor
9	0x81005	Quality control reagent ball is unqualified	Check the reagent ball

7 After-sales Service

7.1 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.)

7.2 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.

7.3 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.

7.4 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.

7.5 After-Sales Service Company Information

Company name: Zhejiang Pushkang Biotechnology Co., Ltd
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