Intellectual Property

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owns the intellectual property rights to this product and this manual.

Without prior written consent , any person or entity is strictly forbidden to use, disclose or allow others to obtain any information in this manual by any means, and any materials contained in this manual shall not be photocopied, reproduced or translated into other languages.

reserves the right to modify and update this manual without prior notice.

reserves the right of final interpretation for this manual.

is registered trademarks of Genrui.

Statement

The current version number of this manual is A/3, released on 2021-07. This manual may be modified as needed without prior notice.

shall be liable for product safety, reliability and performance provided that the following requirements are met:

1) All installation operations, expansions, changes, modifications and repairs of this product are conducted by authorized personnel.
2) All replaceable parts involved in maintenance as well as the related accessories and consumables are original or approved .
3) Any associated electrical equipment complies with national standards and the requirements of this manual.
4) Use and operation of this product are performed in strict accordance with this manual.

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Warranty Service

The entire instrument is covered by a comprehensive warranty for a full year from the date of production. However, damage occurring under the following conditions shall not be covered by this warranty:

1) Man-made damage or damage caused by improper use.
2) Damage caused by mishandling during shipment.
3) Damage caused by uncontrollable natural factors such as earthquake, fire or war.
4) Environment in which the machine is used does not meet the requirements indicated in this manual.
5) Damage caused by use of an unspecified power supply or any other abnormality in the power supply.
6) Damage caused as a result of maintenance performed by personnel not authorized by Genrui.
7) Malfunction of the instrument whose serial number is not legible enough.
8) Malfunction not caused by the instrument itself.

In the event you have any inquiries or questions while using the instrument, you can always contact Genrui.

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Customer Service Department

Manufacturer:	China Care Medical Co Ltd
Address:	4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China
Website URL:	www.chinacaremedical.com
E-mail Address:	
Tel:	+86 1 3 9 2 6 4 8 0 0 4 1
Fax:	

⚠WARNING

- This analyzer can only be operated by test professionals, doctors or laboratory technicians who have been trained by Genrui or its distributors.
- It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or injury of human health.
- Be sure to operate the analyzer under the situation specified in this manual; otherwise, the analyzer will not work normally and the analysis results will be unreliable, which would damage the analyzer components and cause personal injury.

NOTE

- This operation manual is written for the following laboratory professionals:
    1) Daily system operators
    2) Personnel for system maintenance and troubleshooting
    3) Learners for system operation
- When the instrument reaches the retirement period, it is recommended to stop using it or conduct a comprehensive inspection and maintenance before re-using it again.

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Introduction

We would like to sincerely thank you for choosing to purchase o u r product.

Please read this manual carefully in order to ensure correct use of the product. After carefully reading this manual, please keep it safely stored so that you can refer to it when necessary.

Product Name: Fully-auto Specific Protein Analyzer

Model: CC**L**-A**P120**

Safety Classifications: Electric shock safeguard class I, overvoltage category II, pollution class 2

Management Classification: A kind of immunoassay system in the category of analyzing instruments for clinical tests (6840); management category: Class II.

Product Composition: This product primarily comprises a control system, detection system, input-output unit, power and application software.

Scope of Product Application: This product is suitable for use in the analysis of specific protein in human body fluids.

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Manufacturer: China Care Medical

Registered Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China

Date of Manufacture: See the nameplate of the instrument

Instrument Service Life: 8 years

Manual Preparation Date: July 6, 2021

Item No.: P01.91.300373-03

REF 31000003

Manual Overview

This manual is focused on helping users to understand several aspects of the PA120 Fully-auto Specific Protein Analyzer (hereinafter called the analyzer), including safety, installation, structure and function, analysis principles, operating procedures, maintenance and repair, alarms and treatment. Please operate the analyzer in strict accordance with this manual in order to ensure proper use.

Who Should Read This Manual

This manual contains information written for clinical laboratory professionals or trained doctors, nurses or laboratory technicians to:

- Learn about hardware and software of the analyzer.
- Set system parameters.
- Perform daily operations.
- Perform system maintenance and troubleshooting.

How to Find Information

This manual contains 12 chapters and 3 appendices. Refer to the table below to find the information you need.

If you want to…	**Please refer to…**
learn about safety and precautions of the analyzer	Chapter 1 Safety and Precautions for Use
learn about installation requirements of the analyzer	Chapter 2 Installation
learn about the intended use, parameters, structure, operation interface, etc. of the analyzer	Chapter 3 System Description
learn about how the analyzer works	Chapter 4 Working Principles
learn about how to set system parameters, such as date, time, parameters, units, etc.	Chapter 5 System Settings
learn about the sample collection and preparation methods, and sample analysis process	Chapter 6 Sample Measurement
review sample results	Chapter 7 Result Review

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If you want to…	**Please refer to…**
learn about the basic requirements of quality control and how to use the quality control programs provided by the analyzer	Chapter 8 Quality Control
learn about the method of generating calibration curve	Chapter 9 Calibrate
learn about how to service/maintain the analyzer	Chapter 10 Service and Maintenance
learn about how to solve the problems of the analyzer	Chapter 11 Troubleshooting
learn about the transportation and storage methods of the analyzer	Chapter 12 Transportation and Storage
learn about the common consumables and ordering methods of the analyzer	Chapter 13 Commonly-used Consumables and Ordering Method
learn about the technical specifications of the analyzer	Appendix A Specifications
learn about the communication protocol of the analyzer	Appendix B Communication
learn about the hazardous substances that may contain in the analyzer parts	Appendix C Hazardous Substances

Symbols

You will find the following symbols in this manual:

Symbols	**Meaning**
WARNING	Alerts the operator to follow the statement below the symbol while in operation, otherwise it may cause personal injury.
CAUTION	Alerts the operator to follow the statement below the symbol while in operation, otherwise it may lead to analyzer damage or unreliable analysis results.
NOTE	Alerts the operator to follow the statement below the symbol, which emphasizes the important information or special attention to be paid while in operation.

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	Alerts the operator to follow the statement below the symbol, otherwise it may take the risk of potential biohazard.

You may find the following symbols on the analyzer, reagent, QC or calibrator:

Symbols	Meaning
	**Caution**
	**Combustion** Do not use flammable dangerous goods, such as alcohol, ether, etc. near the analyzer.
	**Electric shock** 1) When the power supply is turned on, non-authorized maintenance personnel must not open the analyzer's panel. 2) Do not splash liquid into the analyzer. Once the liquid penetrates into the analyzer, turn off the power immediately and contact Genrui in time.
	**Biohazard** The background color of this symbol is yellow, the symbol itself and the outline is black. 1) Samples, controls, calibrators, etc. are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory. 2) All the waste liquids should be regarded as infectious. Gloves should be worn while contacting with them. All the items contacted with the test samples, such as pipette tips, cuvettes should be regarded as infectious, wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory. 3) All the wastes are potentially infectious and should be regarded as medical wastes and disposed according to the current regulatory requirements.

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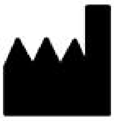
Symbols	Meaning
	Moving parts, please do not reach inside when working
	**High temperature** May cause bodily injury.
	**Corrosion** The cleaning solution is chemically corrosive, protective gloves should be worn while in operation.
~	Alternating current
IVD	For in vitro diagnostic use only
SN	Serial number
	Date of manufacture
	Manufacturer
CE	CE marking. The device is fully in conformance with the Directive 98/79/EC on in vitro diagnostic medical devices
EC REP	Authorized representative in the European Community

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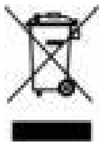
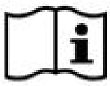
Symbols	Meaning
	The following definition of the WEEE label applies to EU member states only: The use of this symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased the product.
	Consult *Operation Manual*
	This electronic product contains some poisonous and harmful substances. The environmental protection use period is 20 years, after this period, it should be put into the recycling system.

Conventions

All illustrations provided in this manual are used for descriptive purposes or as examples only, not intended to be used for any other purposes. They may not necessarily reflect setup of the analyzer or data displayed.

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1. Safety and Precautions for Use

1.1. Safety

Abide by the following safety precautions when using the analyzer. Ignoring any of these safety precautions may lead to personal injury or instrument damage.

⚠WARNING

- If the system is used in a manner not specified by Genrui, the protection provided by the system may be impaired.

1.1.1 Preventing Electric Shock

Please abide by the following instructions to prevent electric shock.

1) When the main power is on, non-authorized service personnel must not open the rear and side covers of the analyzer.
2) Spilliage of reagent or sample on the analyzer may cause instrument failure and even electric shock. Do not place sample and reagent on the analyzer. In case of spilliage, switch off the power immediately and contact the customer service department of Genrui promptly.

1.1.2 Preventing Personal Injury Caused by Moving Parts

Please abide by the following instructions to prevent personal injury caused by moving parts.

1) Do not touch moving parts, such as sample probe, mixer and reaction disk automatic cleaning mechanism, when the system is in operation.
2) Do not put your finger or hand into the open parts when the system is in operation.

1.1.3 Preventing Personal Injury Caused by Light Source

Please abide by the following instructions to prevent personal injury caused by light sources or barcode scanners.

1) Do not look directly into any beams of light, including those produced by light sources and barcode scanners, as these beams can harm your eyes.
2) Before replacing the light source, disconnect the power supply of the analyzing unit and wait at least 15 minutes until the light source cools. Do not touch the light before cooling, so as not to cause burns.

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1.1.4 Preventing Fire and Explosion

Please abide by the following instructions to prevent fire and explosion.

1) Ethanol is flammable, be careful when using it.
2) Do not use flammable dangerous goods, such as alcohol, ether, etc. near the analyzer.

1.1.5 Preventing Biohazards

Please abide by the following instructions to protect against the biohazardous infection.

1) Incorrect use of sample may lead to biohazardous infection. Do not directly touch the sample, control, calibrator, mixture or waste with your hands. Always wear gloves and lab coat, if necessary, goggles, to avoid being infected.
2) In case your skin contacts the sample, follow standard laboratory safety procedure and consult a doctor.

1.1.6 Preventing Chemical Hazards

Please abide by the following instructions to protect against the chemical infection.

1) Certain reagents, cleaning solutions are corrosive to human skins. Exercise caution when using them.
2) In case your skin or clothes contact the reagents or cleaning solutions, wash them off with soap and clean water. In case the reagents or cleaning solutions spill into your eyes, rinse them with plenty of water and consult an oculist.

1.1.7 Preventing Radiation Hazards

Please abide by the following instructions to protect against the hazardous radiation.

1) Laser used for this analyzer belongs to low power range, with wavelength of 0.4-0.7μm, power less than 1mW, long time watching may cause retinal damage, so take protective measures and use warning signs.
2) The basic principle of laser safety is definitely not to stare into the laser beam, especially the original beam, and do not look at the laser beam reflected by the mirror. To reduce the full expansion of eye pupils, the laboratory lighting should be bright.

1.1.8 Treating Dangerous Substances

Please abide by the following instructions to prevent environmental pollution and personal injury caused by dangerous substances.

1) Incorrect use of samples may lead to the risk of infection. Never touch the sample, mixture and waste directly, always wear gloves. In case your skin contacts the sample, follow standard laboratory safety procedure or consult doctors to take remedial measures.
2) Some reagents are strongly acidic or alkaline. Do not directly touch them with your hands or clothes. In case your hands or clothes contact the reagents, thoroughly wash off the reagent immediately with soap and clean water. If the reagents spill into your

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eyes, rinse them immediately with plenty of water and consult an oculist.

1.1.9 Treating Wastes

Please abide by the following instructions to prevent environmental pollution and personal injury caused by wastes.

1) Some substances in reagent, control, cleaning solution and waste are subject to regulations of contamination and disposal. Dispose of them in accordance with your local or national guidelines for biohazard waste disposal and consult the manufacturer or distributor of the reagents for details.

2) Waste container needs to be placed on a plat area lower than the instrument to prevent waste reflux and poor discharge. Waste generated by the instrument must be specially treated before discharge to the outside environment, cannot be discharged directly to the sewer in order to avoid pollution. Wear gloves and lab coat, if necessary, goggles, to dispose of wastes.

1.1.10 Treating Waste Analyzer

Please abide by the following instructions to dispose of the waste analyzer.

Materials of the analyzer are subject to contamination regulations. When the instrument reaches its lifetime, it should be disposed according to the requirements of the local environmental protection department, cannot be disposed and discarded as common wastes.

1.1.11 Safety Summary

All safety related regulations and instructions that appear on the instrument must be observed to ensure personal safety and to prevent damage to the instrument. If used in a manner not specified by Genrui, the protection provided by the instrument may be impaired.

1.2. Precautions for Use

To use the analyzer safely and efficiently, please pay much attention to the following operation notes.

1.2.1 Intended Use

1) The analyzer is designed for the analysis of specific protein in human body fluids.

2) To draw a clinical conclusion, please also refer to the patient’s clinical symptoms and other test results.

1.2.2 Operator

The analyzer can only be operated by personnel who have been trained and authorized by Genrui or its local distributors for safety purposes.

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1.2.3 Installer and Service Personnel

The analyzer can only be installed, repaired and maintained by personnel who have been authorized by Genrui or its local distributors according to the safety requirements in order to reduce the risks during the whole process.

1.2.4 Consumables

The operators should only use consumables within their expiration date.

1.2.5 Hazardous Substances

The handling, containment and exhaust of hazardous substances should comply with local regulations.

1.2.6 Operating Precautions

Do not open the covers of the reagent/reaction disk and touch the moving parts, such as sample probe, reagent probe, mixer and fan when the analyzer is running.

1.2.7 Improper Operation

Be careful when loading and unloading of samples and regents, otherwise it may affect the test results or cause injury to the operator.

1.2.8 Actions Taken in Case of Failure

If the instrument has dangerous failure, such as fire, odor, smoke, etc., anyone can directly disconnect the power of the instrument or the main power and contact Genrui or its local distributors immediately.

1.2.9 Operating Environment

1) Please install and operate the analyzer in an environment specified by this manual. Installing and operating the analyzer in other environment may lead to unreliable results and even analyzer damage.

2) If the operating environment of the analyzer needs to be modified, please contact Genrui or its local distributors.

1.2.10 Electromagnetic Noise

1) Electromagnetic noise may interfere with operations of the system. Do not install devices generating excessive electromagnetic noise around the system. Do not use such devices as mobile phones or radio transmitters in the room housing the system. Do not use other CRT displays around the system.

2) Do not use other medical instruments around the system that may generate electromagnetic noise to interfere with their operations.

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1.2.11 Device Connection

1) For a device not permanently connected, please do not place it at a location that is hard to disconnect.
2) For all the external switches or breakers and external over-current protection device, it is recommended to place them near the analyzer.
3) Devices connected with the network port of the analyzer should conform to the requirements of National Standards GB4793.1-2007 and GB4793.9-2013 of China as well as IEC60950.
4) It is forbiden to use detachable MAINS supply cord with inadequate rating.

1.2.12 Operating the System

1) Operate the system strictly as instructed by this manual. Inappropriate use of the system may lead to incorrect test results or even system damage or personal injury.
2) Before using the system for the first time, perform the calibration program and then QC program to make sure the system is in proper status.
3) Be sure to run the QC program every time you use the system, otherwise the result may be unreliable.
4) Do not open the covers of the sample disk and reagent disk when the system is in operation.
5) The network interface on the analyzing unit is to be used for connection with the operation unit only. Do not use it for other connections. Only use the supplied cable for the connection.
6) Do not touch the display, mouse or keyboard with wet hands or hands with chemicals.

1.2.13 Maintaining the System

1) Follow instructions in this manual when performing system maintenance. Inappropriate maintenance may lead to incorrect test results, or even system damage or personal injury.
2) To wipe off dust from the system surface, use a soft, clean and wet (not too wet) cloth, soaked with mild soap solution if necessary, to clean the surface. Do not use organic solvents such as ethanol for cleaning. After cleaning, wipe the surface with dry cloth.
3) Switch off all the powers and unplug the power cable before cleaning. Take necessary measures to prevent water ingression into the system, otherwise it may lead to system damage or personal injury.

1.2.14 Setting up the Parameter

1) No need to set parameters such as sample volume, reagent volume and other parameters for the system, all parameters and calibration curves are directly input into the reagent card. Swipe the card corresponding to the appropriate batches of reagents.
2) Comply with the relevant description in this manual and reagent instructions.

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1.2.15 Samples

1) Use samples that are completely free of insoluble substances like fibrin, or suspended matter, otherwise the probe may be blocked.
2) Medicines, anticoagulants, preservatives, hemolysis, icterus or chylomicron in the samples may lead to unreliable test results.
3) Store the samples properly. Improper storage may change the compositions of the samples and lead to unreliable results.
4) Sample volatilization may lead to incorrect results. Do not leave the sample open for a long period.
5) Certain samples need to be processed before being analyzed by the system. Consult the reagent manufacturer or distributor for details.
6) The system has specific requirements on the sample volume. Refer to this manual for details.
7) Load the sample to correct position on the sample disk before the analysis begins. Otherwise you will not obtain correct results.

1.2.16 Reagents and Controls

1) When using this system for analysis, use appropriate reagents and controls.
2) Select appropriate reagents according to performance characteristics of the system. Consult the reagent suppliers, Genrui or its authorized distributor for details, if you are not sure about your reagent choice.
3) Store and use reagents and controls strictly as instructed by the suppliers. Improper storage of reagents and controls may lead to unreliable results and bad performance of the system even within the validity period.
4) Swiping the reagent card to perform a calibration after replacing reagents. Otherwise, you may not obtain accurate results.
5) Contamination caused by carryover among reagents during analysis may affect test results. For more information about carryover of reagents, please consult the reagent manufacturer or distributor.
6) The reagent disk has cooling function, but if not need to use the reagents for a long time, remove them from the instrument and store them according to the requirements of reagent instructions.

1.2.17 External Equipment

External equipment connected to the system, such as computer and printer, shall be consistent with CCC (S&E). Using unsuitable external equipment may cause system malfunction or personal injury.

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2. Installation

2.1. Overview

The analyzer is checked and packed with care before it is shipped from the factory. Inspect the carton carefully after arrival. If any sign of damage is found, contact Genrui or your local distributor immediately.

2.2. Installer

The analyzer should only be installed by Genrui personnel or Genrui-authorized distributor. Users should provide appropriate environment and space for the installation. When the analyzer needs to be relocated, please contact Genrui or Genrui-authorized distributor. When you received your analyzer, please immediately notify Genrui or its authorized local distributor.

2.3. Checking before Installation

Inspection for Damage

All the analyzers have been inspected strictly by Genrui before packing and shipping. When you received your analyzer, before opening the packaging, perform a thorough inspection and note whether there is any of the following damage:

1) Up-side-down or distortion of the packaging.
2) Obvious water marks on the packaging.
3) Obvious signs of being striked on the packaging.
4) Packaging shows signs of having been opened previously.

If you notice any of the above instances of damage, please immediately notify Genrui or Genrui-authorized local distributor.

If the outer packaging is intact, unpack it in the presence of Genrui staff and/or authorized distributor personnel, and conduct the following inspection:

1) Check all the parts against the packing list contained inside the packaging.
2) Check the surface of all the parts for any crack, strike or distortion.

If you notice any shipment damage or missing part, please immediately notify Genrui or Genrui-authorized local distributor.

Packing List

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Check all the parts according to the packing list contained inside the packaging. If you notice any missing part, please immediately notify Genrui or its authorized local distributor.

2.4. Installation Requirements

2.4.1. Environmental Requirements

2.4.2. Power Supply

- Power supply: 100-240V~, 50/60Hz, voltage fluctuation ± 10%.
- The instrument should be connected to a properly grounded power socket.
- The protective ground terminal on the rear of the instrument must be connected to the ground and, if possible, to a dedicated ground cable. Users have the obligation to ensure the reliability of the power supply at the analyzer's working site.
- Frequent power failure will greatly degenerate the performance and reliability of the analyzer. Users should choose an optional backup DC power supply or equip the uninterruptible power supply (UPS) by themselves.
- Be sure to use the specified fuse only. Fuse specification: F6.3AL250.

⚠WARNING

- Make sure the power socket is grounded correctly. Improper grounding may lead to electric shock and/or instrument damage.
- Be sure to connect the instrument to a power socket that meets the above mentioned requirements and has a proper fuse installed.

2.4.3. Site and Space

- The instrument is for indoor use only.
- The bearing platform (or ground) should be level with gradient less than 1/200 and be able to bear the weight of 100kg.
- The bearing platform (or ground) should be free of vibration.
- The environment should be free of dust, corrosive gas and flammable gas as far as possible.
- The environment should not be in direct sunlight and not be close to heat and wind sources.
- The instrument should not be placed near brush-type motors and electric contact devices that are frequently powered on and off.
- Do not use such devices as mobile phones or radio transmitters near the instrument. Electromagnetic waves generated by those devices may interfere with operation of the

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instrument.

⚠CAUTION

- The environment should be well ventilated. Use ventilation equipment if necessary. The wind source should not blow over the instrument directly, as this might affect reliability of the data.

2.4.4.Temperature, Humidity and Atmospheric Pressure

- Ambient temperature: 10℃-30℃
- Ambient humidity: ≤ 85%
- Atmospheric pressure: 70.0kPa-106.0kPa

⚠CAUTION

- Strictly follow the specified environmental requirements to store and use the instrument. Otherwise, you may not obtain reliable results.
- If the ambient temperature and humidity does not meet the specified requirements, be sure to use air-conditioning equipment.

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2.5. Water Supply and Drainage Requirements

2.4.5. Water Supply Requirements

1) The quality of water supplied to the instrument should comply with CAP Class 2 water standards.
2) Water supply volume: No less than 2.5L/hour.
3) If using water purification equipment, the water supply must be gravity-based.
4) The distance between the water supply device and inlet of the instrument should not exceed 2 meters.

2.4.6. Drainage Requirements

1) Follow local environmental regulations to discharge waste.
2) Connection to Waste Collection Container: The waste collection container can be placed on a horizontal surface below the instrument, it is important to ensure that the waste collection container be positioned lower than the waste liquid outlet on the left panel of the instrument.
3) Connection to Wastewater Tubing: The waste liquid discharge port must be within 12cm higher than the ground.

- Treat waste liquid discharged by the analyzer according to your local waste emission standards.

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2.6. Connecting the Analyzer System

2.4.7. Connecting Power Cable

Make sure the power switch of the analyzer is turned off. Plug one end of the power cable into the analyzer’s power interface, another end into the power socket.

2.4.8. Connecting Ground Terminal

Directly connect the equipotential earthing terminal at the rear of the instrument to the earth wire through a ground lead.

2.4.9.Connecting COM RS232

If the analyzer needs to be connected with the hospital laboratory information system (LIS) or the whole hospital information system (HIS), take out the serial port cable and connect one end to COM RS232 at the rear of the analyzer and the other end to the computer. Set the serial port according to the instructions of LIS or HIS. For information about the communication protocol, refer to *Appendix B*.

2.4.10. Connecting Network Port

If the analyzer needs to be connected with the hospital laboratory information system (LIS) or the whole hospital information system (HIS), take out the network cable and connect one end to the network port at the rear of the analyzer and the other end to the hospital LAN. Complete the LIS communication setting according to the LAN configuration. For the detailed settings, refer to 5.12.

2.4.11. Connecting Barcode Scanner

If the analyzer needs to connect with the barcode scanning device, directly connect the barcode serial port cable to the USB interface at the rear of the analyzer.

2.4.12. Connecting Optional Devices

There are USB interfaces on the back and side of the analyzer, which can be connected to other devices such as keyboard or mouse.

2.4.13. Connecting the Tubing Assembly

Remove the protective caps on the back of the analyzer and take out the reagents, waste container and rinse/water/waste connection tube assembly. Connect one end of the tube to the corresponding position on the back of the analyzer and the other end into the appropriate reagent and waste containers. Make sure that there is no looseness and distortion of the tubing connections.

2.4.14. Installing the Printing Paper

1) Slightly press to open the cover of the built-in printer.

2) Take out the empty scroll and put in a new one, make sure the free end is at the bottom.

3) Put one end of the paper roll into the printer head (i.e., between the metal plate and black plastic printer head), the printing paper is drawn in and one end is revealed through the printer head’s narrow slot.

4) Close the cover of the built-in printer and pull the paper out from the exit.

This label appears near the printer head. Contact with the printer head and its surrounding metal parts can cause scald. Turn off the analyzer and wait for 20 minutes to replace the printing paper.

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3. System Description

3.1. Overview

This chapter mainly introduces basic functions, test items, structure and composition, basic operations of the interfaces, reagents and consumables of the analyzer.

NOTE

- To draw a clinical conclusion, please also refer to the patient's clinical symptoms and other test results.

3.2. Function Overview

By clicking on the "Menu" button in the lower left corner of the main interface, the operator can enter the corresponding interface to achieve the various functions. To perform the required operations, select the corresponding buttons by referring to the following table.

Realized functions	**Function button**
Perform sample analysis	Measure
Set system parameters	Set
Review analysis results	Review
Running the quality control program	QC
Maintain/service the analyzer	Service
Debugging instrument	Debugging (password required)
View version information	Version About
Turn off the analyzer	Shutdown

Table 3-1

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3.3. Structure and Composition

The analyzer consists of the control system, detection system, input and output section, power supply and application software.

3.3.1 Front View of the Analyzer

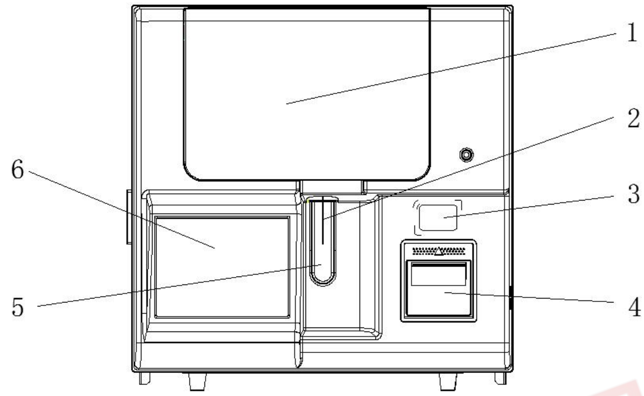

Figure 3-1

1--Front window 2--Sample probe 3--Magnetic induction area

4--Built-in printer 5--Aspirate key 6--Touch screen

The sample probe tip is sharp and may contain biohazardous materials. Pay attention to avoid contact with the probe when working around it.

3.3.2 Modules Inside the Window

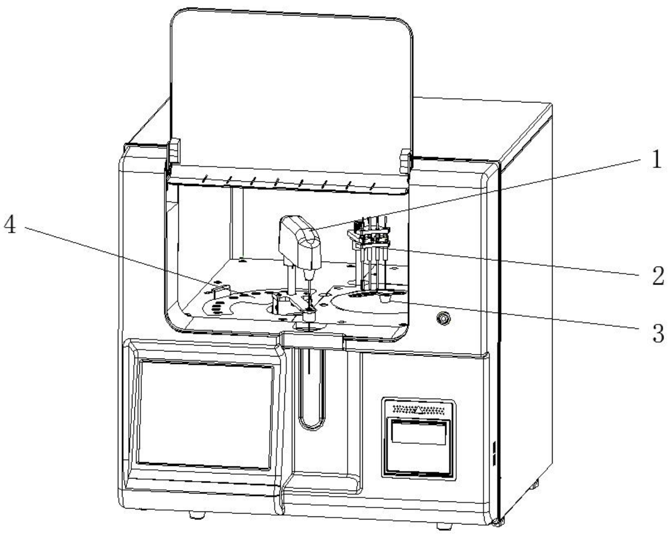

Figure 3-2

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1--Sample probe rocker　2--Washing needles　3--Reaction disk　4--Reagent disk

3.3.3 Left Side View of the Analyzer

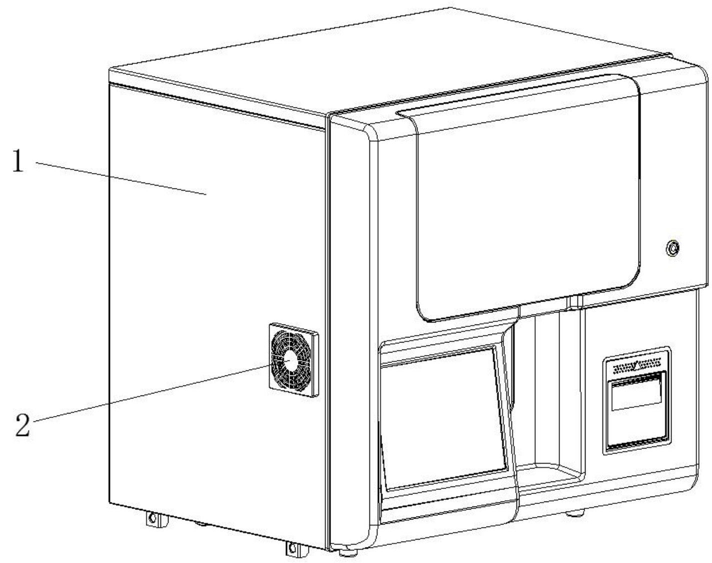

Figure 3-3

1--Circuit side door　2--Cooling fan

3.3.4 Right Side View of the Analyzer

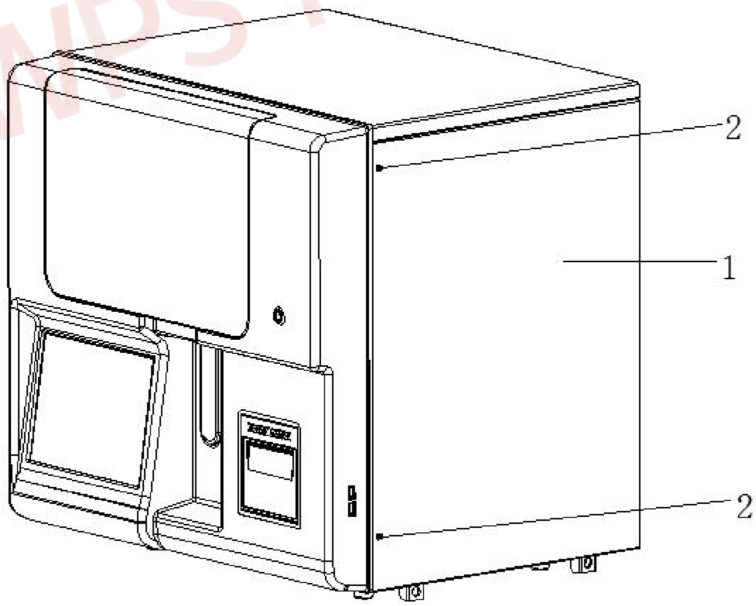

Figure 3-4

1--Fluid path side door　2--Fixing screw

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3.3.5 Back View of the Analyzer

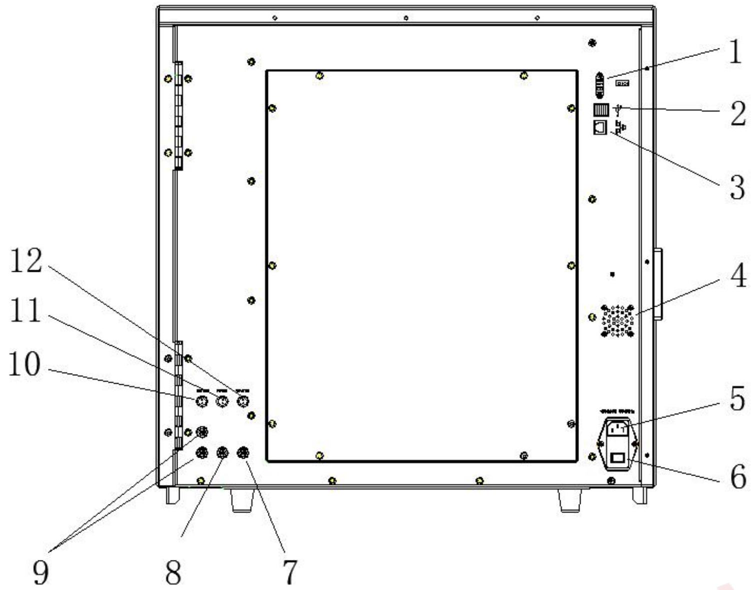

Figure 3-5

1--RS232 serial port	2--USB interface	3--Network interface
4--Fan	5--Power cable interface	6--Power switch
7--Waste interface	8--Rinse interface	9--Water interface
10--Water sensor interface	11--Rinse sensor interface	12--Waste sensor interface

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⚠WARNING

- The analyzer must be used under a good condition of grounding.
- To avoid electric shock, disconnect the power cable before maintenance.
- To prevent fire, use fuse with a specified type and current.

3.4. Operation Interface

After entering the system, the operation interface defaults to the main measurement interface. There are six shortcut function buttons on the top of the interface: Measure, Review, QC, Calibrate Service and Print, you can switch to the corresponding interface by clicking the buttons. The bottom left corner of the interface is the “Menu” button, through which you can enter the corresponding interface to achieve the various functions.

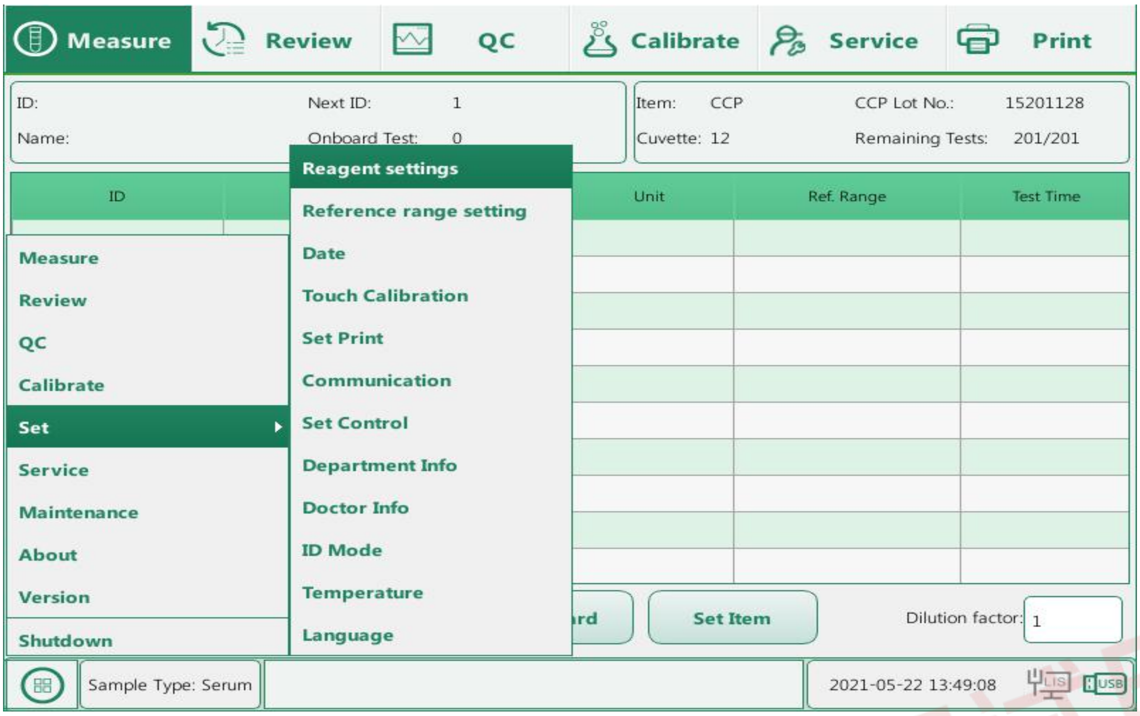

Figure 3-6

3.5. Reagents and Controls

The analyzer loads supporting reagents automatically, the reagents used are as follows:

3.5.1 Antibody (antiserum)

The antibody (antiserum) can only react to a particular antigen, without cross reaction to other antigens.

3.5.2 Buffer

The buffer solution acts as a medium for the antigen-antibody reaction.

3.5.3 Diluent

Diluent is used to pretreat the sample, making it meets the test requirements.

3.5.4 Controls

Controls are used for quality control of the instrument. They are available in low, normal and high levels.

3.5.5 Calibrator

The calibrator is used for calibration of the calibration curve, and is divided into three levels: high, medium and low.

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4. Working Principles

4.1. Overview

The analyzer uses nephelometry to measure the concentration of specific proteins. According to Rayleigh scattering formula, under a certain condition, the scattered light is proportional to the particle concentration.

4.2. Measuring Principle

The analyzer takes the two-point method of immunonephelometry to do a rapid quantitative analysis.

1) Principle

When a light of a certain wavelength illuminates horizontally to pass the solution, it meets the antigen-antibody complex particles, and then it is refracted and deflects. There is a very close relationship between the light’s deflection angle and the light’s wavelength, sizes and amount of antigen-antibody complex particles. The intensity of scattered light is proportional to the complex content, namely, the more the testing antigen, the more the complex formed, the stronger the scattered light.

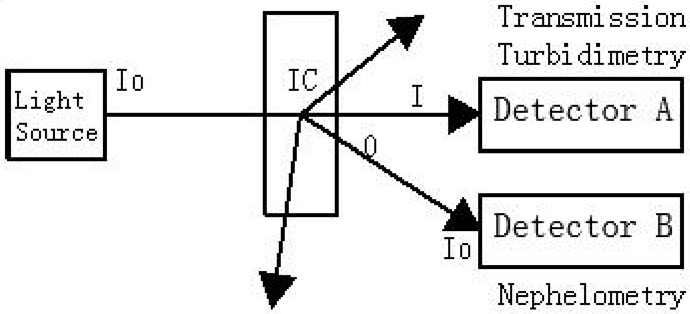
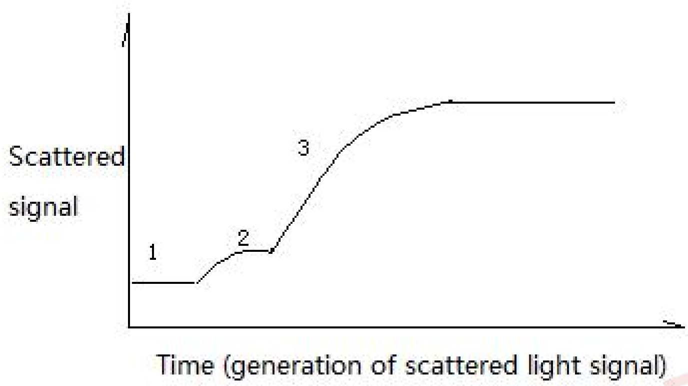
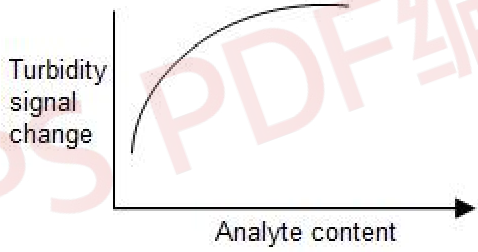


Figure 4-1 Principle diagram

Within a specific reaction stage, the reaction speed is in direct proportional to the first power of the analyte concentration, and in this time, the increase (or decrease) amount of the absorbance is directly proportional to the analyte concentration. Fix the testing time, draw the standard curve based on the corresponding absorbance increase amount of standard substances with different concentrations during this time. The analyzer tests the absorbance increase amount of the sample, and then calculates the sample concentration according to the standard curve.





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2) Calibration type

Calibration type of the analyzer is Logit-5P, supporting multiple algorithms.

The calibration parameters are directly input into the reagent magcard, no need to calibrate again.

Calibration formula: $R = R_0 + \frac{K}{1 + e^{(-a + b\ln C + cC)}}$

There are 5 parameters, namely R_0, K, a, b and c. To calculate all the parameters by iterative method, at least 5 standard solutions are required.

5. Settings

5.1. Overview

The initial settings of the analyzer are made at the factory, so all the interfaces are system defaulted at the first start up. However, users can reset some parameters to satisfy their different requirements in practical application. Click “Set” in the menu to enter the setting interface, as shown in Figure 5-1:

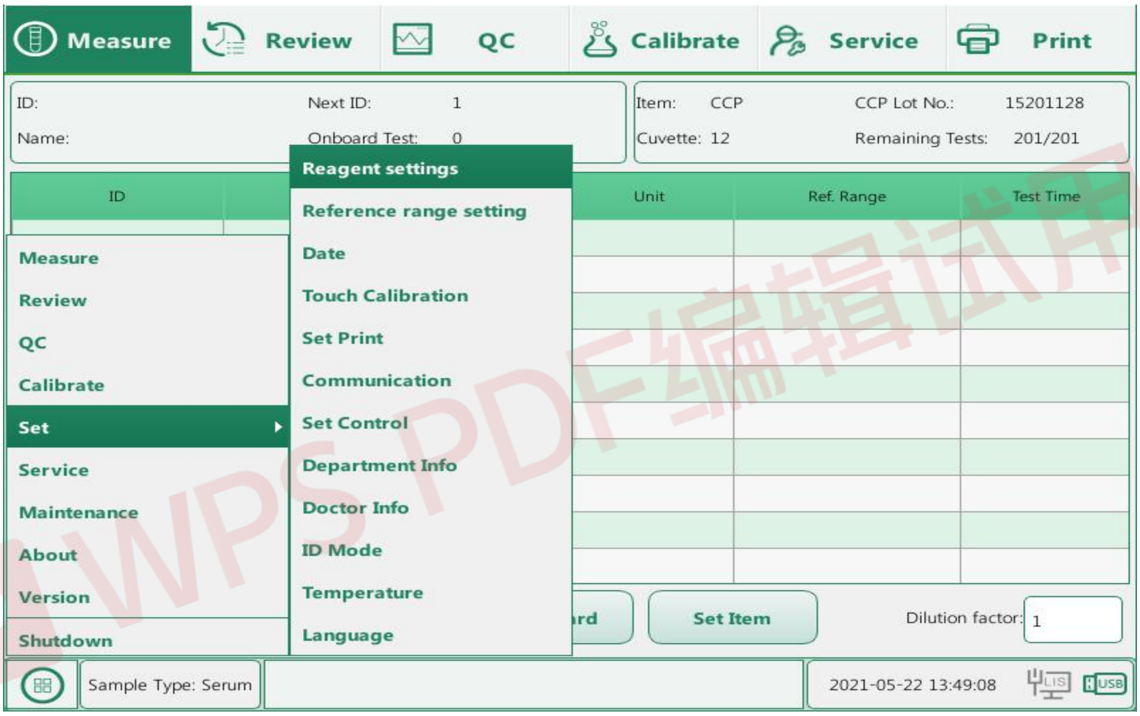

Figure 5- 1

5.2. Reagent

There are a total of 10 reagent positions, numbered sequentially from 1 to 10 in a clockwise direction. By changing the setting of reagent positions, placement of reagents for each item in the reagent disk can be changed.

Click “Set” > “Reagent” in the menuto enter the reagent test interface, as shown in Figure 5-2.

Figure 5-2

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5.2.1 Reagent settings

Select any item bar, the “Reagent” button is activated, click “Reagent” to enter the following settings interface:

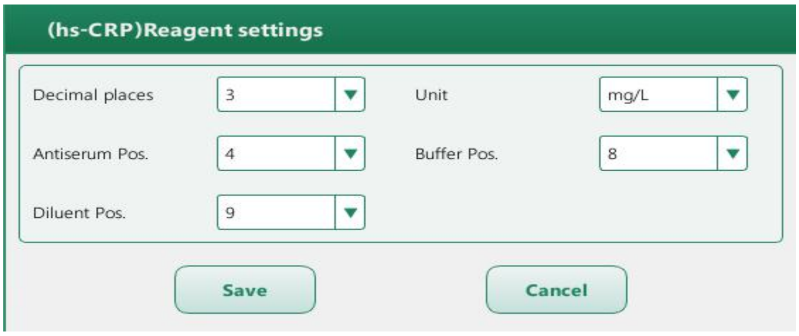

Figure 5-3

The “Decimal places” and “Unit“ of the item can be set according to the clinical situation.

Click the drop-down triangle to set the reagent position, where the optional diluent position is 9 or 10; the optional buffer position is 5, 6, 7 or 8; the optional antibody position is 1, 2, 3 or 4.

5.2.2 Query

Click the “Query” button to enter the query window as shown below:

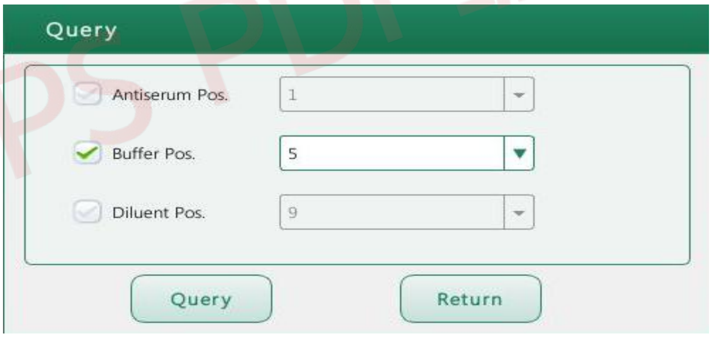

Figure 5-4

WPS PDF编辑试用

Select the appropriate reagent, if you check the box before the buffer and enter 5 for the position, click “Query” to search out all the items with buffer position set to 5, as shown below:

Item	Min	Max	Antiserum Pos.	Buffer Pos.	Diluent Pos.	Remaining Tests
CCP	0.000	30.000	1	5		0
Cys-C	0.000	1.160	1	5		0
FDP	0.000	5.000	1	5		0
SAA	0.000	10.000	1	5		0
saa(pre)	0.000	10.000	1	5		0
IgM	0.400	2.300	1	5		0
NGAL	37.000	180.000	1	5		0
TRF	2.000	3.600	1	5		0
C4	0.100	0.400	1	5		0

Figure 5-5

WPS PDF编辑试用

5.2.3 Default

Click the “Default” button, a dialog box pops-up asking if you want to set the reagent position as the default reagent position, click “Yes” to restore the default settings, click “No” to cancel.

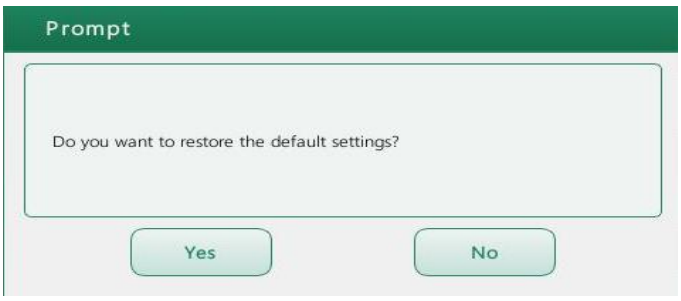

Figure 5-6

5.3. Reference range setting

Click the “Set”-“Reference range setting” in the menu, to enter the following setting interface:

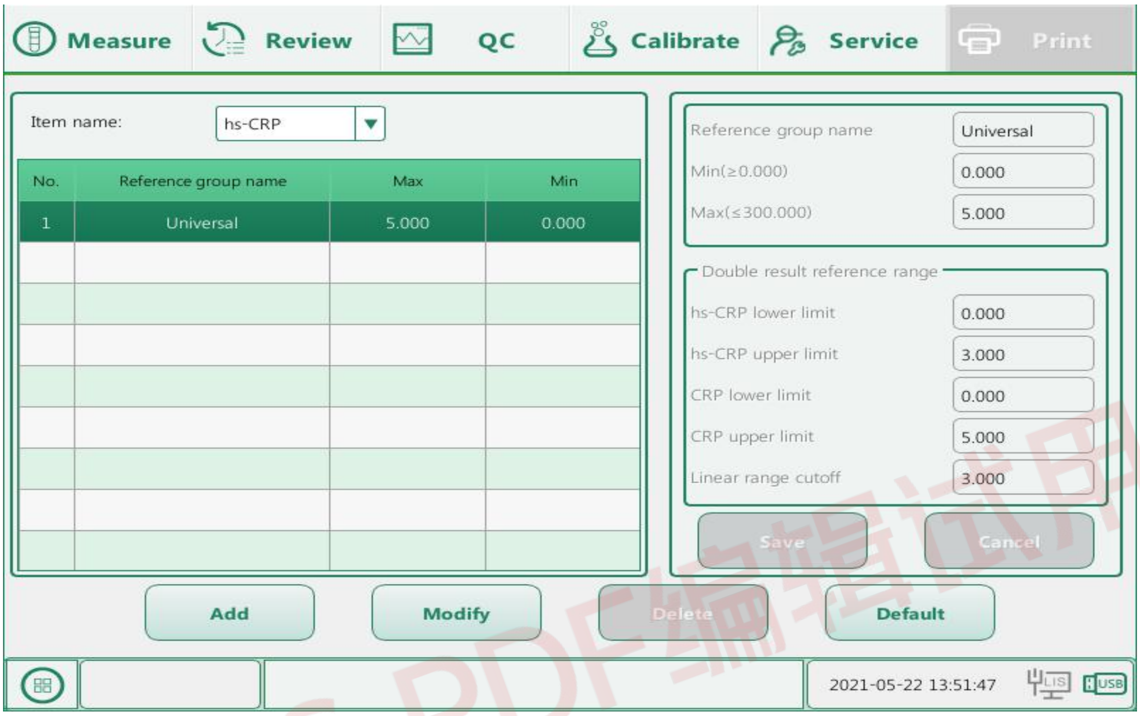

Figure 5-7

The upper limit and lower limit of the reference range of the item can be set according to the clinical situation. The upper and lower limits of the reference range are set from 0 to the upper limit of the linear range.

The hs-CRP (p-hs-CRP) item can set the "Double result reference range", and other items have no duouble result reference range. The hs-CRP (p-hs-CRP) item can set the "upper limit", "lower limit" and "Linear range cutoff" of the reference range according to the clinical situation. Linear range cutoff is the dividing point between hs-CRP and the linear range of CRP. Linear range cutoff is set to be greater than or equal to the upper limit of the hs-CRP double result reference range and less than the upper limit of the CRP double result reference range.

Click the drop-down box of the Item name to switch items.

Add: Click the "Add" button to add a reference group. After setting a new reference group, click "Save" to add successfully, and click "Cancel" to cancel the addition.

Modify: Select the reference group and click the "Modify" button to modify the reference range. After the modification, click "Save" to make the modification successful, and click "Cancel" to cancel the modification.

Delete: Select the reference group, click the "Delete" button, and a pop-up window will pop up with "Delete data cannot be restored. Do you want to delete the selected reference

WPS PDF编辑试用

group", click "Yes" to delete the reference group, click "No" to not delete.

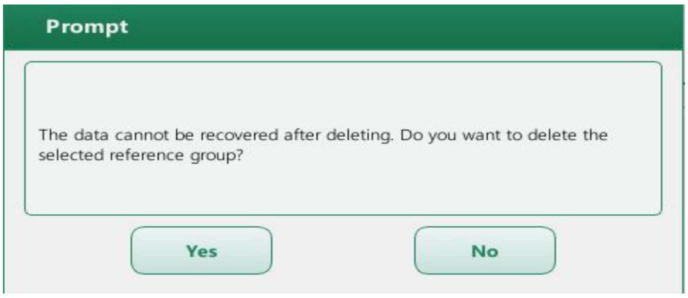

Figure 5-8

Default: select the general reference group, click the "Default" button, a pop-up window of "Do you want to restore the default settings?" pops up, click "Yes" to restore the default reference range, click "No" to not restore.

5.4. Date&Time

Click the “Set”-“Date” in the menu to enter the system time setting interface:

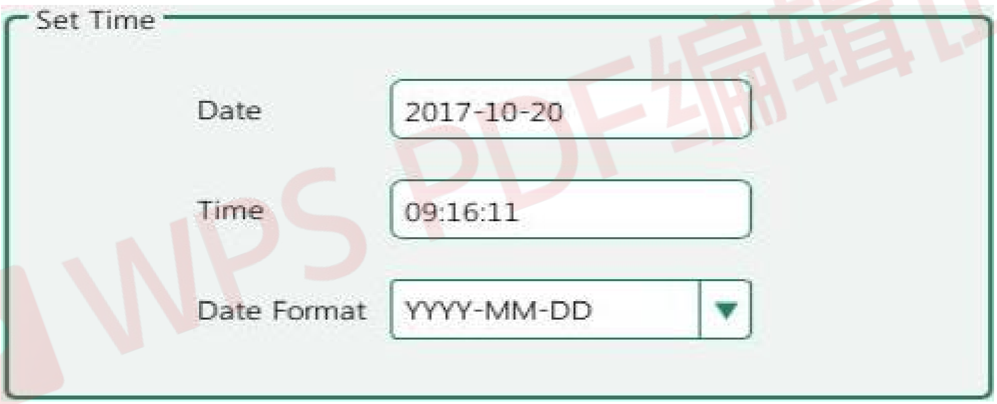

Figure 5-9

Click the date or time you want to modify, the input keyboard pops up, modify the time and date. You can select the date format via the drop-down triangle.

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5.5. Touch Screen Calibration

Click the "Set"-"Touch Calibration" in the menu, as shown in the following figure, and then click the icons that appear on the screen to complete the screen calibration.

Figure 5-10

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5.6. Communication Settings

Click “Set” > “Communication” in the menu to enter the communication setting interface, as shown in Figure 5-11. The operator can complete the protocol and transmission mode settings.

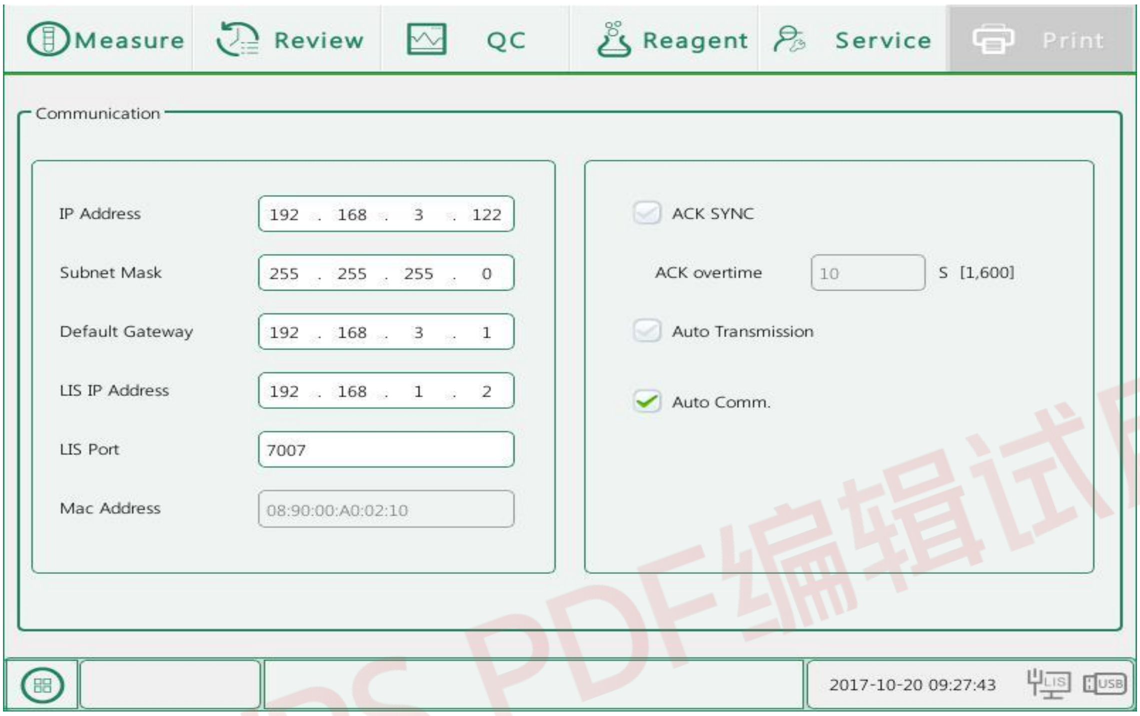

Figure 5-11

■ Protocol settings

Click the “IP Address”, “Subnet Mask” and “Default Gateway” edit box to enter the correct IP address, subnet mask and default gateway.

Click the “LIS IP Address” edit box to enter the correct IP address of the LIS server.

Click the “LIS Port” edit box to enter the communication port number that the LIS server listens on.

■ Transmission mode

The operator can activate the relevant communication settings by clicking the desired option in the checkbox as needed:

ACK SYNC: Upload data successfully after receiving the response from LIS server.

ACK overtime: It is considered to upload data unsuccessfully when not received the LIS server response data within a set time.

Auto Transmission: Upload the sample when the LIS server is not connected and upload it automatically (up to 50 samples) after the connection is successful.

Auto Comm.: Automatically upload data to LIS server after normal sample measurement is complete.

5.7. Print Settings

Click “Set” > “Print” in the menu to enter the print setting interface, as shown in Figure 5-12.

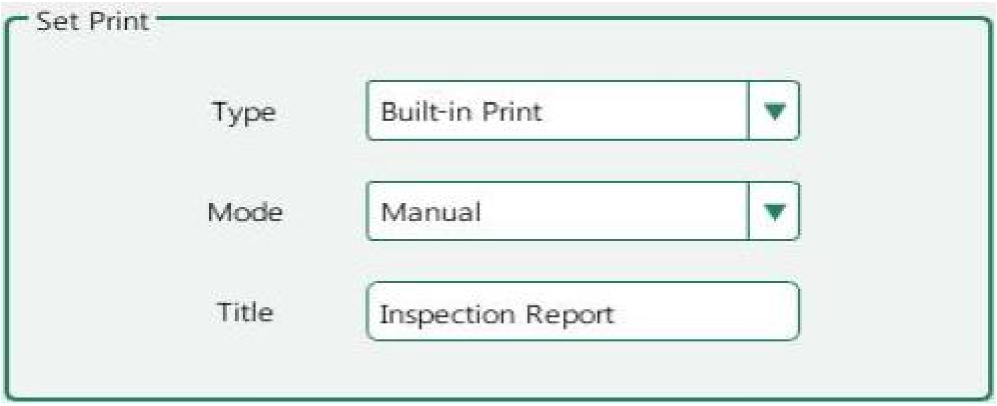

Figure 5-12

5.7.1 Print Type

- Built-in Print

Select “Built-in Print” to print through the thermal printer of the analyzer.

- External Print

Select “External Print” to print through an external printer. After connecting an external printer, the printer model appears, get the printing paper ready, then you can do the printing.

5.7.2 Print Mode

- Auto

Select “Auto” to print results automatically after completion of the sample test.

- Manual

Select “Manual”, results will not be printed after the sample test, but you can click the “Print” button in the main measurement interface or enter the review interface to print results.

5.7.3 Print Title

Enter a desired report title in the “Title” text box.

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5.8. Control Settings

Click “Set” > “Control” in the menu to enter the control setting interface, as shown in Figure 5-13.

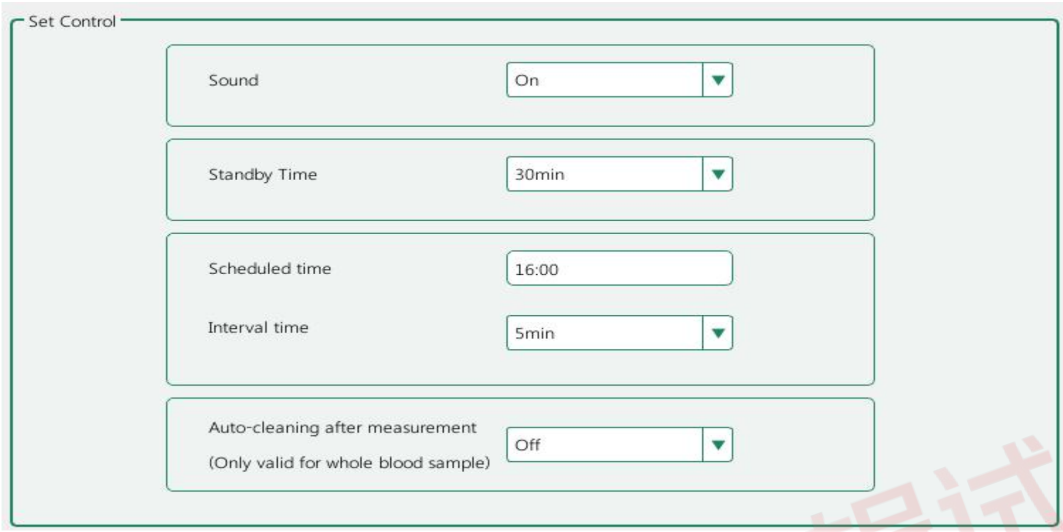

Figure 5-13

5.8.1 Alarm Setting

Click the “Sound” drop-down menu to set the alarm. You can set the alarm “On” or “Off” when a failure occurs.

5.8.2 Screensaver Setting

Click the “Standby Time” drop-down menu to set the standby time. When the instrument is in the main measurement interface without any operation, the instrument will automatically clean all cuvettes when the set standby time is reached, after the cleaning is completed, the instrument enters the standby mode and the screen shows the system standby status. To use the instrument again, simply touch the screen to exit the standby mode.

Figure 5-14

WPS PDF编辑试用

5.8.3 Scheduled Maintenance Setting

In the text box of "Scheduled time", you can set the time point for daily maintenance. Click the "Interval time" drop-down menu to set the interval time for the scheduled maintenance reminder to pop up again after the scheduled maintenance is cancelled. The scheduled maintenance reminder can be manually cancelled 3 times. When the scheduled maintenance time is reached for the 4th time, and the scheduled maintenance sequence is not affected, the instrument is forced to enter the scheduled maintenance sequence.

5.8.4 Auto-cleaning after measurement

Click the "Auto-cleaning after measurement" button and select on or off. When the instrument changes from the measurement state to the test\fault state, automatic cleaning can be performed or not (only valid for whole blood samples).

5.9. Department Information

Click “Set” > “Department Info” in the menu to enter the department setting interface, as shown in Figure 5-15.

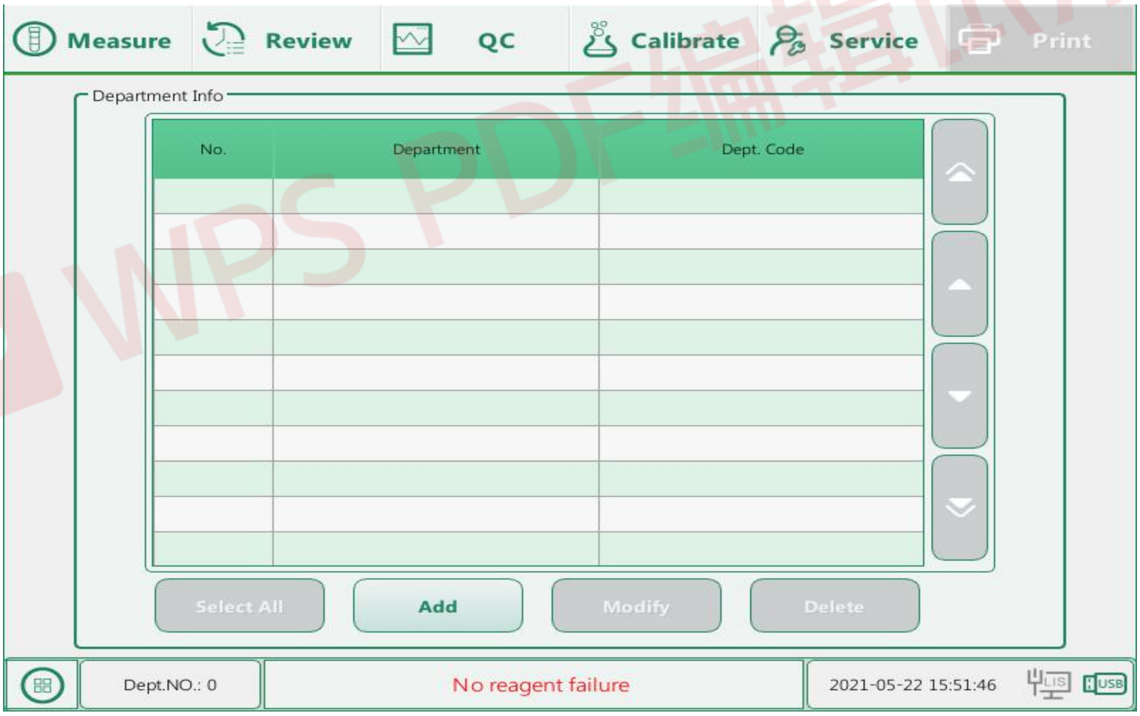

Figure 5-15

- Click the "Select All" button to select all department information options.
- Click “Add” to enter the department information adding interface, as shown in Figure 5-16. Enter the department name and code (i.e. quick input code of the department).

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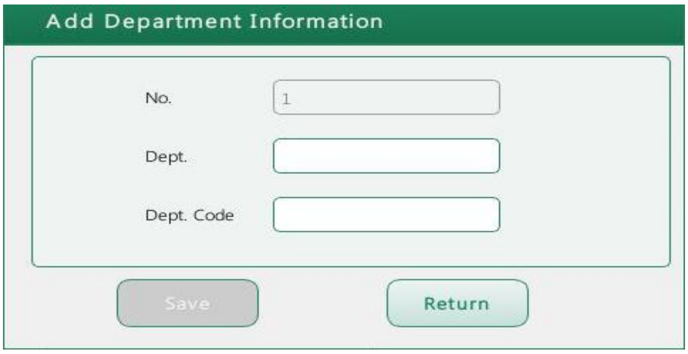

Figure 5-16

Click “Save” to save the settings.

Click “Return” to return to the setting interface.

- Click the corresponding number, the “Modify” and “Delete” button are available, you can modify or delete information.

Figure 5-17

Figure 5-18

5.10. Doctor Information

Click “Set” > “Doctor Info” in the menu to enter the doctor information setting interface, choose to add, modify or delete doctor information.

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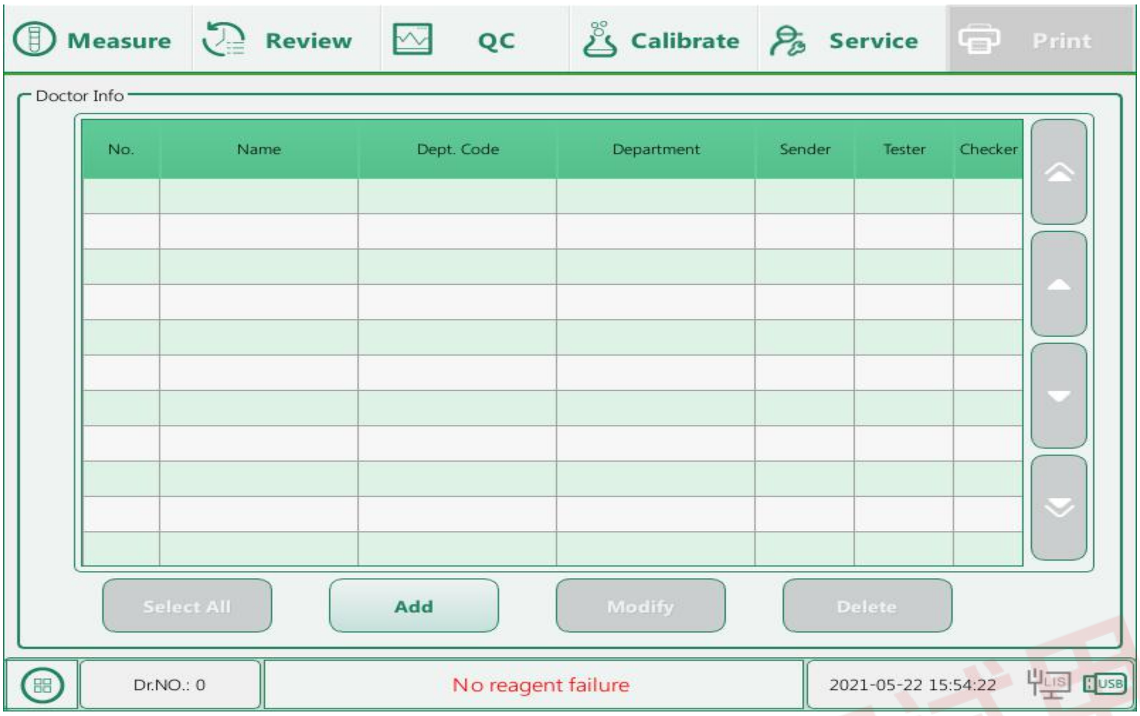

Figure 5-19

- Click the "Select All" button to select all doctors' information.
- Click the corresponding number, the “Modify” and “Delete” button are available, you can modify or delete information.

Figure 5-20

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Figure 5-21

- Click “Add” to enter the doctor inforamtion adding interface, as shown in Figure 5-22. Enter the doctor name and code.

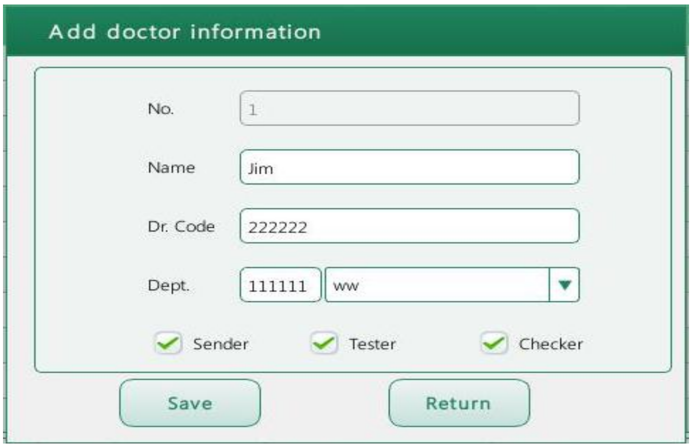

Figure 5-22

You can select the doctor’s work status: Sender, Tester or Checker.

Click “Save” to save the settings.

Click “Return” to return to the setting interface.

5.11. ID Mode

Click “Set” > “ID Mode” in the menu to enter the following interface.

Figure 5-23

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5.11.1 Automatic Mode

Select the ID auto-increment mode, in the main measurement interface, directly insert the keyboard, enter the ID number and press Enter, or scan to input the ID number with a scanner, you can also enter the “Next Sample” interface, the request interface is as shown below:

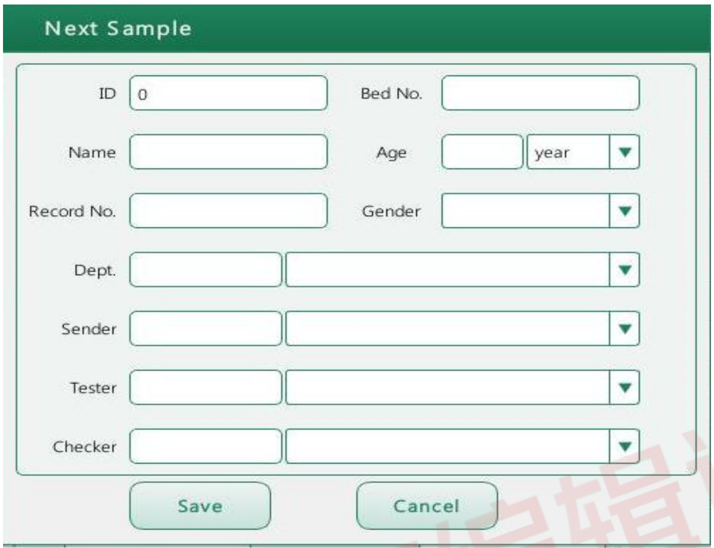

Figure 5-24

After entering the ID, the main interface shows the next ID, which will update the set ID number, continue to the next sample number will plus 1 based on the current ID number.

5.11.2 Request Mode

Click “Request”, the interface for applying for a test is as follows:

Figure 5-25

Click the “Add” button to enter the following menu, input the ID number and sample

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information, click the "Save" button to save the information. In this mode, the ID will not increase automatically, after the requested sample is tested, it is necessary to request again when you want to do sample test again, otherwise the instrument can not do the test.

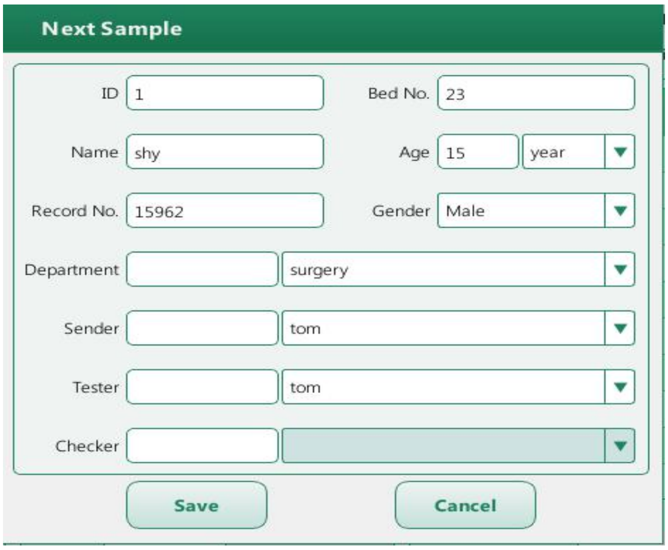

Figure 5-26

5.12. Temperature Settings

The temperature setting menu displays the temperature of the reaction disk and reagent disk. You can manually set the temperature of reaction disk and reagent disk. Click the "Read" button on the right side to read the actual temperature of the reaction disk/reagent disk. After entering the temperature value, click the "Write" button to write the temperature of the reaction disk/reagent disk.

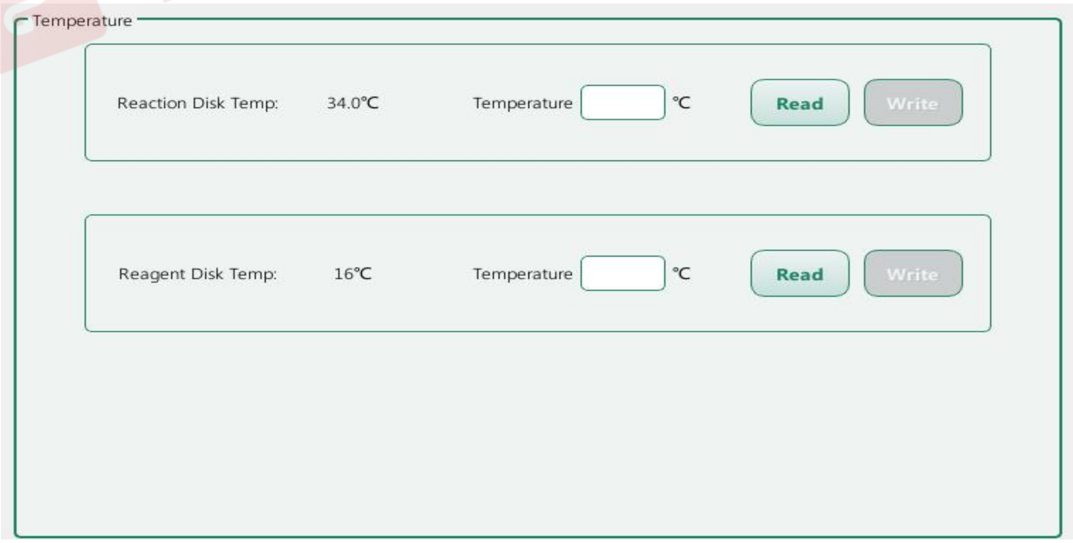

Figure 5-27

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5.13. Language Settings

The language setting menu can be used to switch the system language, four languages to choose from Chinese, English, .French and Spanish.

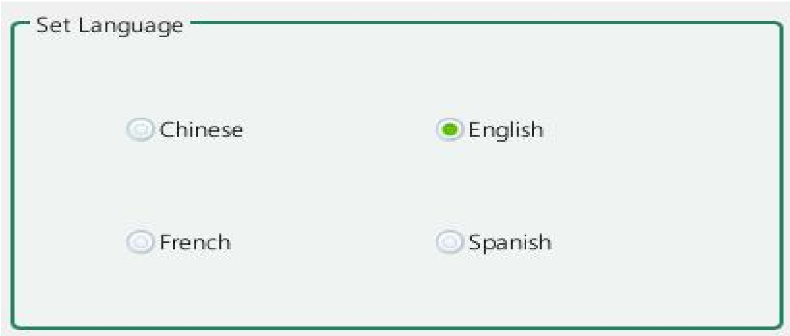

Figure 5-28

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6. Measurement

6.1. Initial Checks

Perform the following checks before turning on the analyzer.

- Check to make sure that the water and rinse solution tubes at the rear of the instrument are properly connected and their remaining volumes are sufficient.
- Check to make sure the waste container is not full, if full, deal with it in time.
- Check to make sure the power cable, sensor line, ground terminal or other devices are properly connected.
- Open the reagent disk cover and check to make sure that the reagent bottle cap has been opened to prevent the sample probe from collision when starting up the analyzer.

6.2. Preparation for Analysis

Place the reagent into the reagent disk according to the set reagent position. If the reagent is insufficient, add it immediately.

6.3. Starting Up

Before startup, if the analyzer is equipped with an external device such as a scanner, first turn on the power of the external device and make sure it is ready, then turn on the power switch at the rear of the analyzer. The analyzer starts initializing, as shown in Figure 6-1:

Figure 6-1

WPS PDF编辑试用

6.4. Main Measurement Interface

After the instrument is initialized, it will enter the main measurement interface.

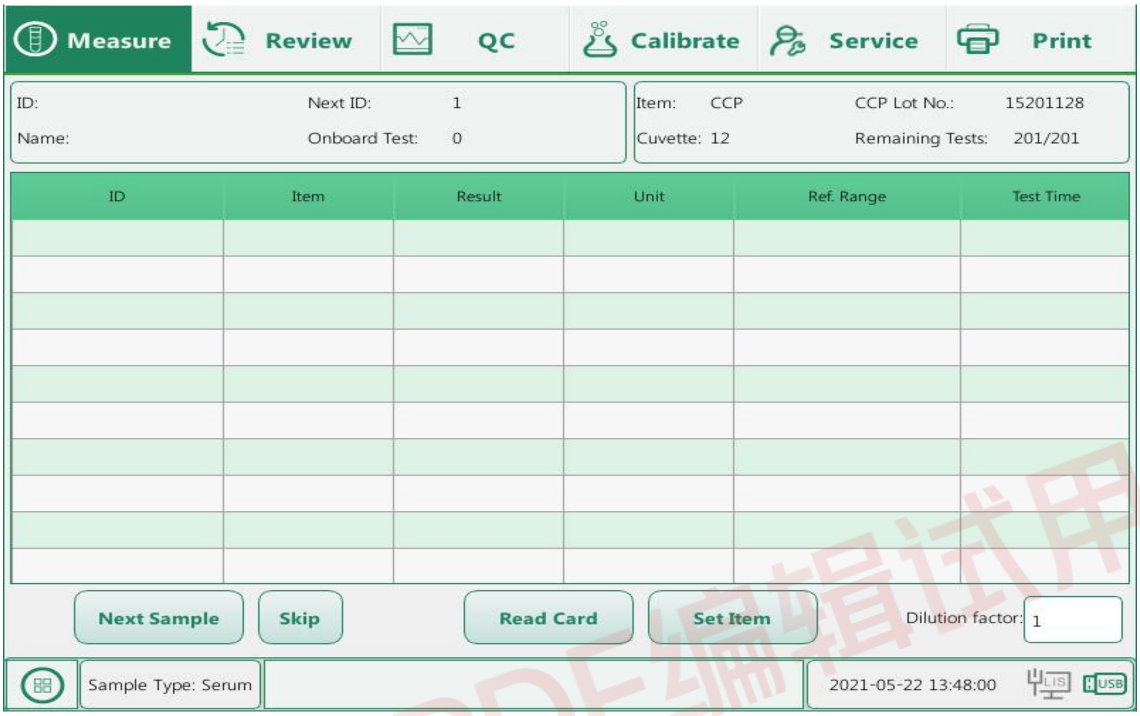

Figure 6-2

6.4.1 Information Display Area

This area displays the current ID number of the test, the next ID number, the name, the onboard tests, the item, the lot number, the cuvette number and the remaining tests.

6.4.2 Result Display Area

This area displays the currently completed test item, the ID number, the result, the unit, the reference range and the test time.

6.4.3 Print

Print the current results.

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6.4.4 Next Sample

Click the “Next Sample” button to enter the sample request interface. If the current setting is ID request mode, perform batch request before testing, you can enter the “Next Sample” editing interface only all the requested tests are completed. If the current setting is ID self-added mode, you can edit the patient information of the next sample during the test. Take ID self-added mode as an example, the patient information interface of the next sample is as follows:

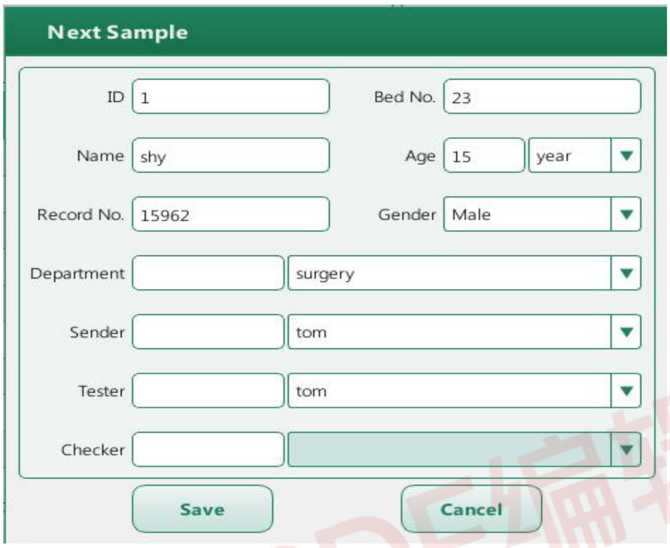

Figure 6-3

Edit the patient information, enter the name, age, medical record number, etc., and then click the “Save” button to save the information.

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6.4.5 Read Card

Click the "Read Card" button, magnetic card information of the currently selected item displays, as shown below:

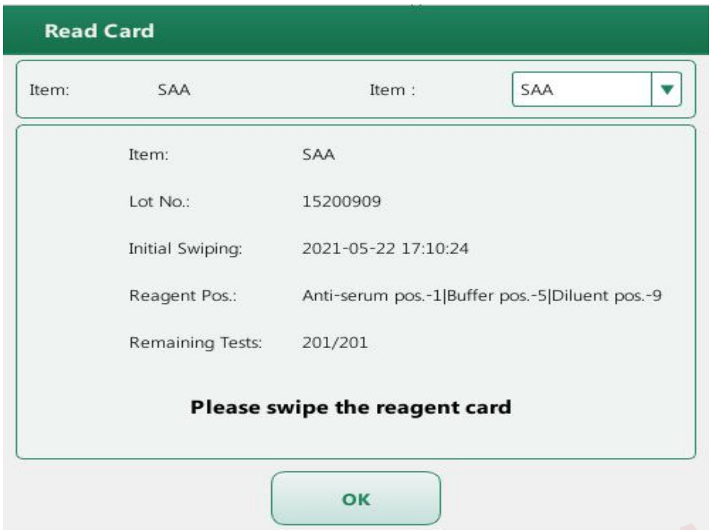

Figure 6-4

If you want to read a new card, place the card onto the magnetic induction area, when the card is swiped successfully, the Item, Lot No., Initial Swiping, Reagent Pos. and Remaing Test will be displayed on the interface.

Figure 6-5

If you want to test the combined items, click the drop-down button on the upper right corner to select the items, and then swipe the card, do not have to switch to the corresponding item. For a single item test, the current item is displayed by default as the item of which the card needs to be read, it is not allowed to switch to other items in the reading card interface. To read card of other items, you can switch items in the item setting interface, and then read the card of the corresponding item.

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6.4.6 Set Item

Enter the item setting interface, you can switch test items and select the appropriate sample type. If the selected item does not support the sample type, it is grayed and unselectable.

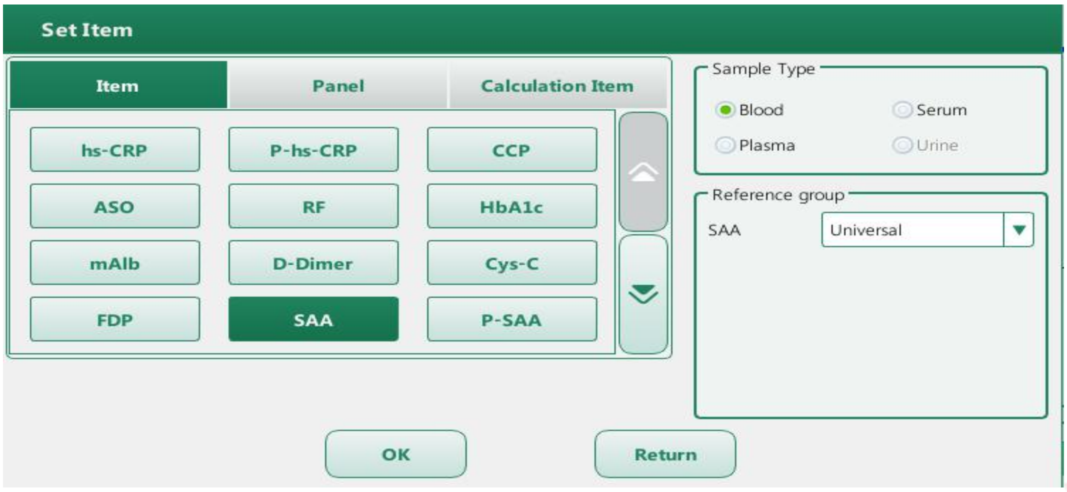


Figure 6-6

■ Single item

Test a single item. Wherein hs-CRP represents testing CRP in normal mode and hs-CRP(pre) represents testing CRP in prediluted mode. The prediluted test item SAA(pre) is also added, in this mode, the samples need to be manually diluted according to the requirements of the predilution reagent instructions.

■ Panel

When testing multiple items with the same sample, click the “Panel” button to enter the combination item test menu, click on the corresponding panel name and select the sample type to complete the test.

■ Calculation item

The calculation items are as shown below:

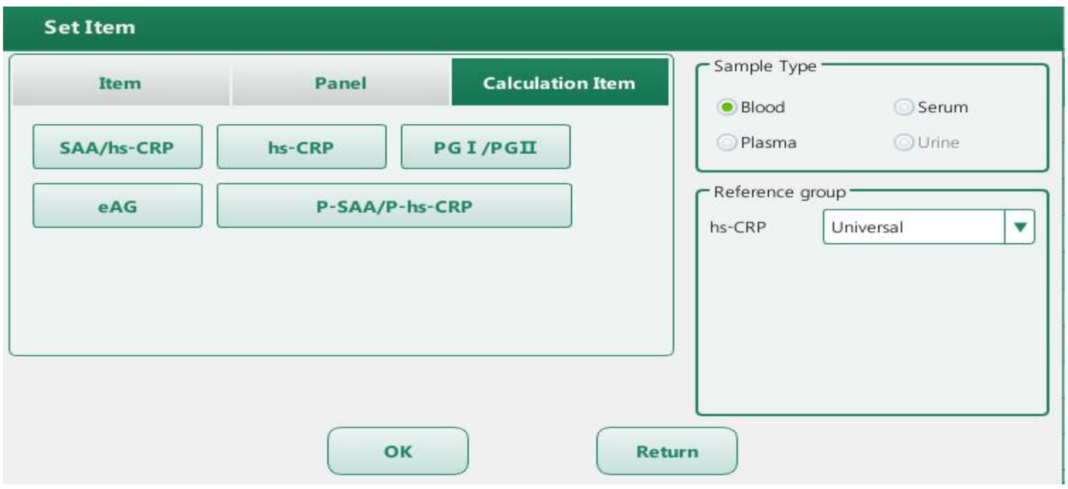


Figure 6-7

WPS PDF编辑试用

SAA/hs-CRP: Test the results of SAA and hs-CRP in the normal mode and output the ratio.

SAA(pre)/hs-CRP(pre): Test the results of SAA(pre) and hs-CRP(pre) in the prediluted mode and output the ratio.

hs-CRP: Can output two results.

PGI/PGII: Select Gastric in the “Panel” tab and PGI/PGII in the “Calculation Item” tab, the test results of PGI and PGII can be output and the ratio displays.

eAG: Test results of e antigen (Facilitating Antigen).

6.4.7 Dilution factor

Applicable to the scene of dilution outside the machine, the interface display value = measurement result * dilution factor (dilution factor range 1-99).

Edit limit of dilution factor:

1) Only numbers can be input, the maximum length is 2, and the default value 1 will be restored when the input is empty;
2) Revert to the default value 1 after each measurement;
3) During the sequential operation, the dilution factor cannot be edited;
4) The expansion item does not support external dilution, so when any expansion item is selected, the dilution factor cannot be edited.

WPS PDF编辑试用

6.4.8 Menu Bar

■ Menu Bar

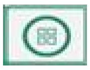
Click , the main menu pops up.

Figure 6-8

■ Sample Ttype

Display the type of sample selected for the current test item.

WPS PDF编辑试用

■ Alarm Prompt Area

Prompt alarm information, click to pop up the fault elimination menu, you can eliminate the fault or view the processing recommendations.

If the waste liquid is full, the pure water is empty or the rinse is empty, the alarms can be automatically canceled if the problems are solved. The remaining alarms can be eliminated by clicking the “Remove Fault” button according to the prompt of “Help Info”.

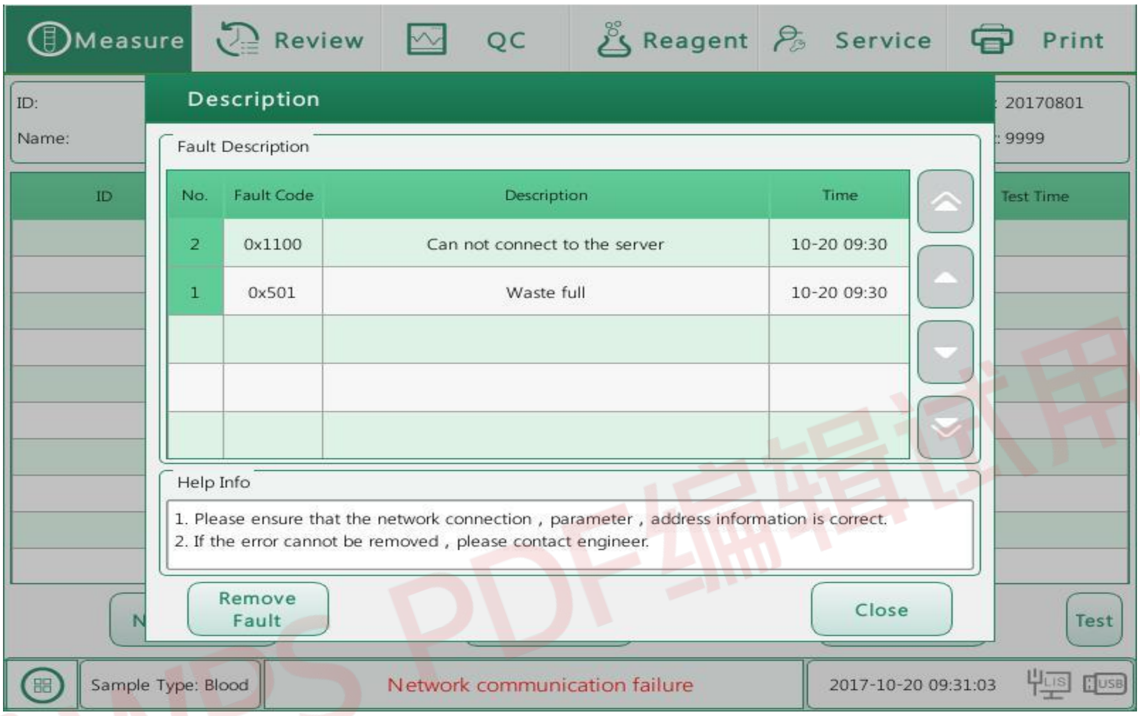
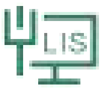


Figure 6-9

■ System Time

Display the current system time, can be modified through the setup menu.

■ LIS Server Connection Icon 

When LIS server is connected with the instrument, the second icon in the lower right corner of the interface is displayed in green, otherwise it is grayed out.

■ USB Connection Icon 

Insert the USB device, the icon will light up when the connection is successful, otherwise, it is grayed out.

WPS PDF编辑试用

6.4.9 Sample Analysis

Select the required test item, enter the setting menu, observe the reagent position of the item and place the reagent for this item into the corresponding reagent position.

- If the lot number of this item has not yet been recorded, you are prompted to swipe the card. Enter the reagent information by referring to the reagent lot number entry method in this manual. If reagent information of this item has been recorded, you can skip this step.
- Select the sample type in the item setting interface according to the type of sample prepared.
- Click the "Next Sample" button in the main measurement interface, enter the ID number of the sample, edit the patient information, save and return to the main measurement interface.
- Place the sample under the sample probe and press the aspirate key, the analyzer completes the sample aspiration and analysis automatically. The onboard tests are displayed at the top of the screen. The analyzer automatically completes the analysis process.

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- During the test, the sample probe is not in the initial position. Before other sample loading actions are completed, buttons in the main menu are locked and you cannot perform other operations at this time. When the sample probe returns to the aspirating position, you can continue to test the next sample, switch items or change the sample type to continue the tests.
- After the test result comes out, it will be displayed in the result display area on the screen.
- All test results can be queried in the review menu and can be edited or modified in the "Details" submenu of the review menu.
- If set to auto print, the test results will be printed automatically. If the printer runs out of paper, the screen will prompt "Printer out of paper". Please replace the paper according to the method provided in this manual.

⚠WARNING

- When the analyzer is running, do not touch its moving parts, such as sample probe, reaction disk, washing probe, fan, etc.
- When replacing reagents, the remaining reagent cannot be poured into the new reagent container, to avoid cross-contamination.

- All the samples, controls, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

6.5. Version Information

6.5.1 Version

Click “Version” in the menu to view the detailed version information about the instrument.

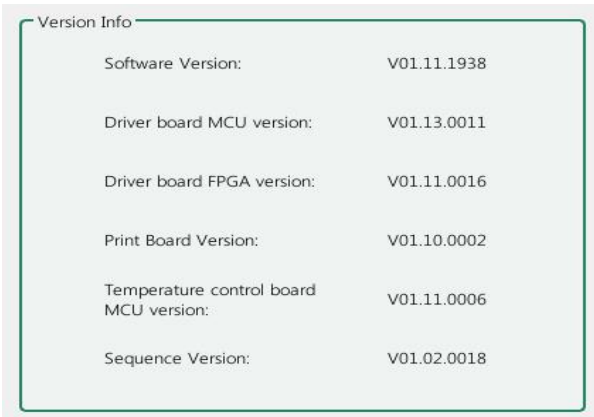

Figure 6-10

WPS PDF编辑试用

6.5.2 About

Click “About” in the menu to view the release version and the full version information.

Figure 6-11

6.6. Shutdown

6.6.1 Shutdown Procedure

At the end of the day's testing, in order to ensure the normal use of the analyzer, it is recommended to perform the shutdown procedure before powering off the analyzer. During the shutdown process, the analyzer will carry out daily maintenance and pipeline cleaning.

Click “Shutdown” in the main menu, a prompt box pops up.

Figure 6-12

Click “Yes” to start cleaning the cuvettes.

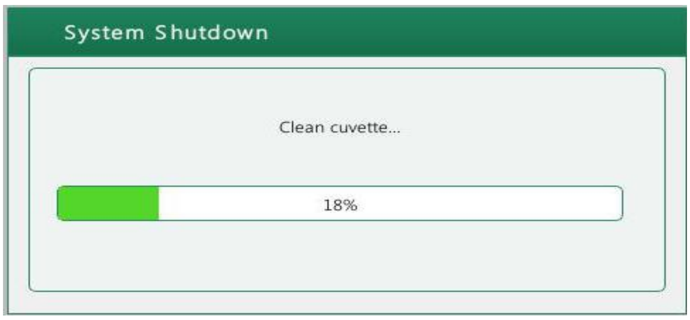

Figure 6-13

WPS PDF编辑试用

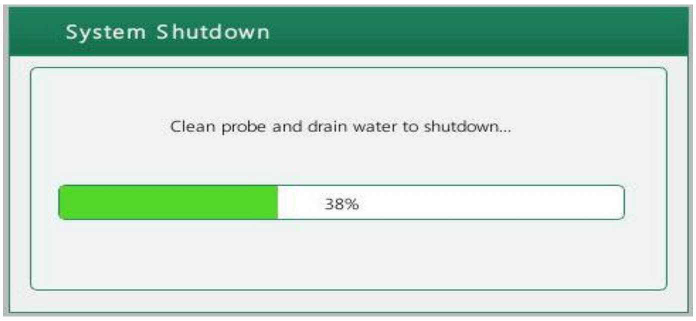

Figure 6-14

After completing the above actions, the system prompts to turn off the power.

6.6.2 Powering Off the Analyzer

Once the shutdown program completes, the screen prompts you to turn off the power. Turn off the power switch on the back of the analyzer to shut it down.

If the analyzer needs to be used frequently, put the caps back on the reagent containers and keep the containers in the reagent disk, the instrument can automatically refrigerate the reagents.

If the analyzer is left unused for a long period of time, remove all reagents from the reagent disk, put the caps back on the reagent bottles and properly store them according to the relevant methods in reagent instructions.

WPS PDF编辑试用

NOTE

- Barring special circumstances, do not turn off the power of the analyzer directly without running the shutdown program.
- If a major failure occurs, turn off the power of the analyzer directly.

7. Review

7.1. Overview

After every test, the analyzer automatically stores the test data. You can query and print the test data through the review interface. The analyzer can store up to 100000 test records and realize unlimited storage by connecting to the laboratory information system.

7.2. Result Review

Click the “Review” button in the main menu to enter the result review interface, as shown in Figure 7-1. There are shortcut buttons at the top of the interface. The menu bar from top to bottom displays the No., the sample ID, the name, the sample type, 5 items, date and time. Their corresponding contents are displayed on the right side of the interface.

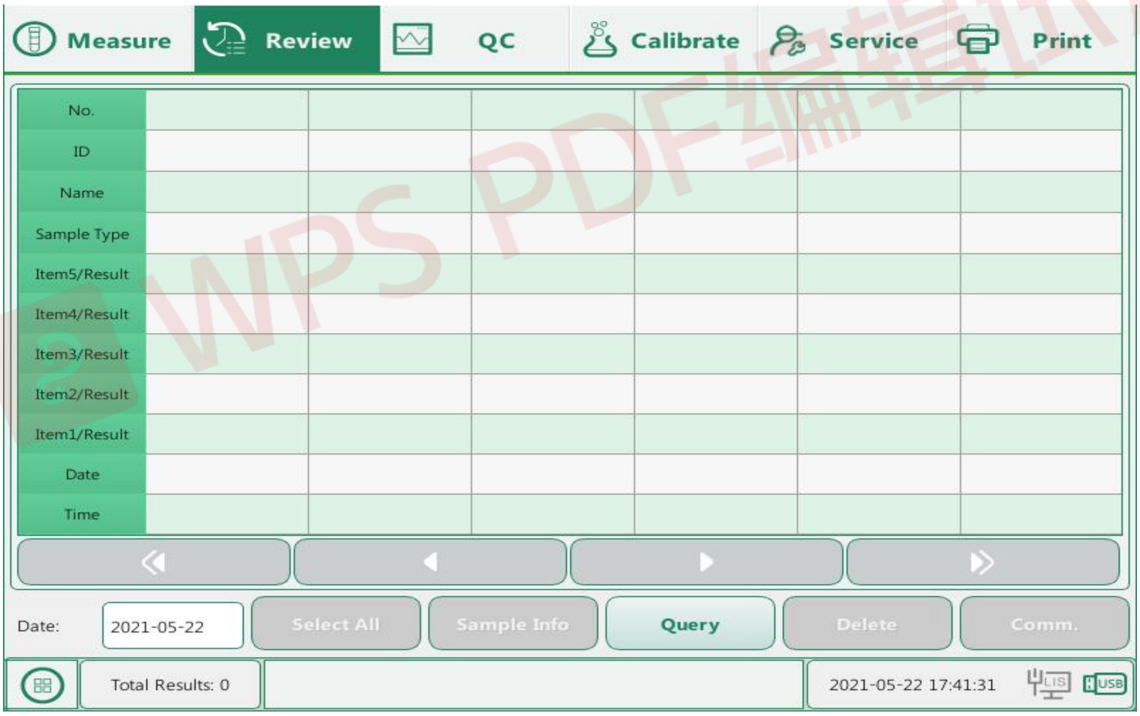

Figure 7-1

- Click the Previous one or the Next one button to view the historical results of the same test date. Click the Previous page or the Next page button to view in pages. You can change the test date directly or input a condition to query results.
- Click “Select All” to select the 6 results on the current interface.
- Click to select the result and click “Delete” to delete the selected result.
- Click to select the result and click “Print” to delete the selected result.

WPS PDF编辑试用

- After selecting a single sample result, click “Sample Info”, the result information displays, you can edit the information, as shown in Figure 7-2.

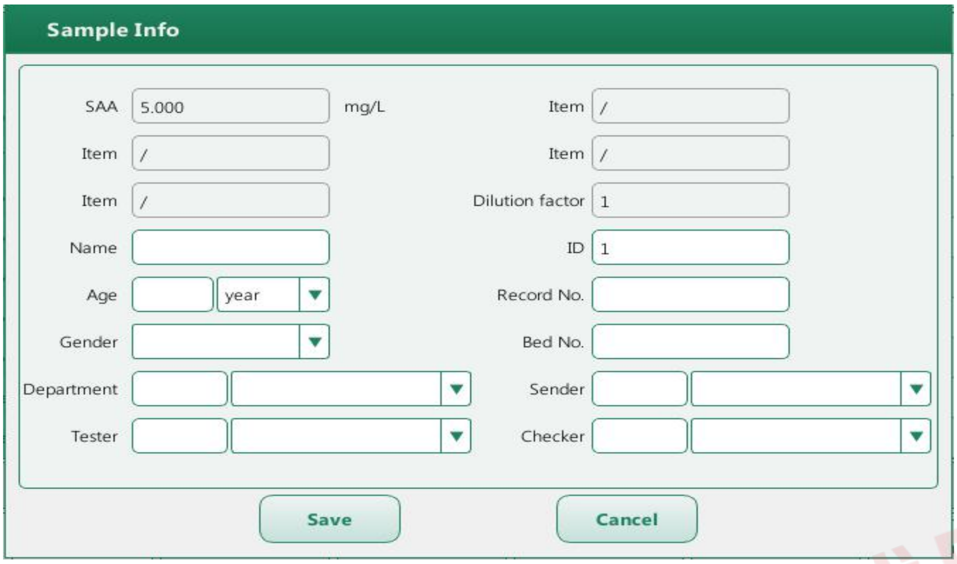

Figure 7-2

You can modify the department, sender, tester or checker, enter the corresponding number in the white box or click  to select it.

Click “Save” to save the information.

Click “Cancel” to return to the result review interface without saving the information.

WPS PDF编辑试用

7.3. Result Query

In the Review interface, click the “Query” button to enter the result query window, as shown in Figure 7-3.

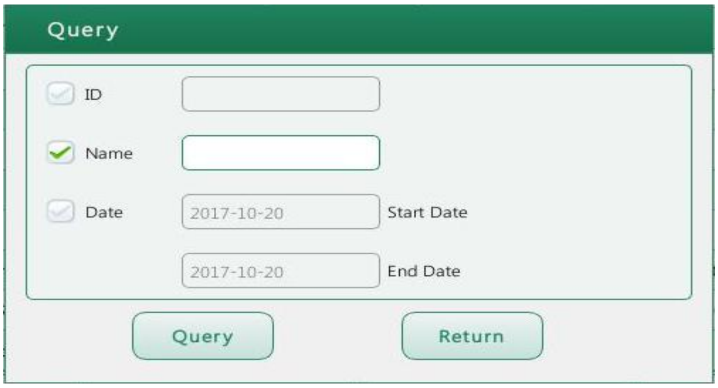

Figure 7-3

- Click “ID”, this button will be selected, enter the sample ID, and then you can query the result according to the sample ID.
- Click “Name”, this button will be selected, enter the sample name, and then you can query the result according to the sample name.
- Click “Date”, this button will be selected, select the start and end date to query the result.
- Click “Query” to display the selected and input results.
- The above query functions can be selected individually or in combination. It is important to note that only when the button of the query condition is selected and the background is green, that you can query by the options, enter only the query condition but not select the corresponding button, the query will be invalid.
- Click “Return” to return to the main menu.

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8. Quality Control

Quality Control (QC) program provided by the analyzer provides a reliable and effective method for detecting and preventing system errors that may exist. To always maintain accurate analysis results, identify and eliminate system errors in time, it is recommended to run the QC program with the controls every day.

8.1. QC Settings

Click the “QC” button on the top of the main interface or click “QC” > “Set QC” in the menu to enter the QC setting interface. There are six buttons on the bottom of the interface. The first three button functions are the “Add”, “Select All” and “Delete” opertation to the QC files. The last three button functions are available only after one of the QC files is selected, then you can switch to the “QC Test”, “QC Graph” or “QC List” interface respectively and switch between them.

WPS PDF编辑试用

Figure 8-1

NOTE

- Use the controls dedicated for this analyzer, such as the controls provided by Genrui or its approved control products of other brand. Using other controls may lead to incorrect QC results.
- Store and use the controls as instructed by instructions for use of the controls.
- Do not use deteriorated or expired controls.

In the QC interface, click “Add” to enter the QC file editing interface, as shown in Figure 8-2.

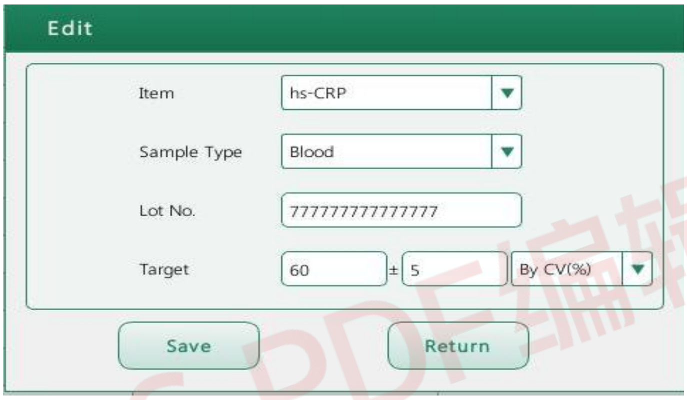


Figure 8-2

- Select the newly added QC item and sample type.
- Input “Lot No.” and “Target”, select “By CV(%)”.
- Click “Save” to save the current QC file.
- Click “Return” to return to the QC setting interface.

8.2. QC Test

Select a QC file in the QC interface and click “Measure” button to enter the QC test interface. If the currently tested item is different from the item of the selected QC file, the instrument will automatically switch the item. Place the control under the sample probe and press the aspirate key to start QC analysis.

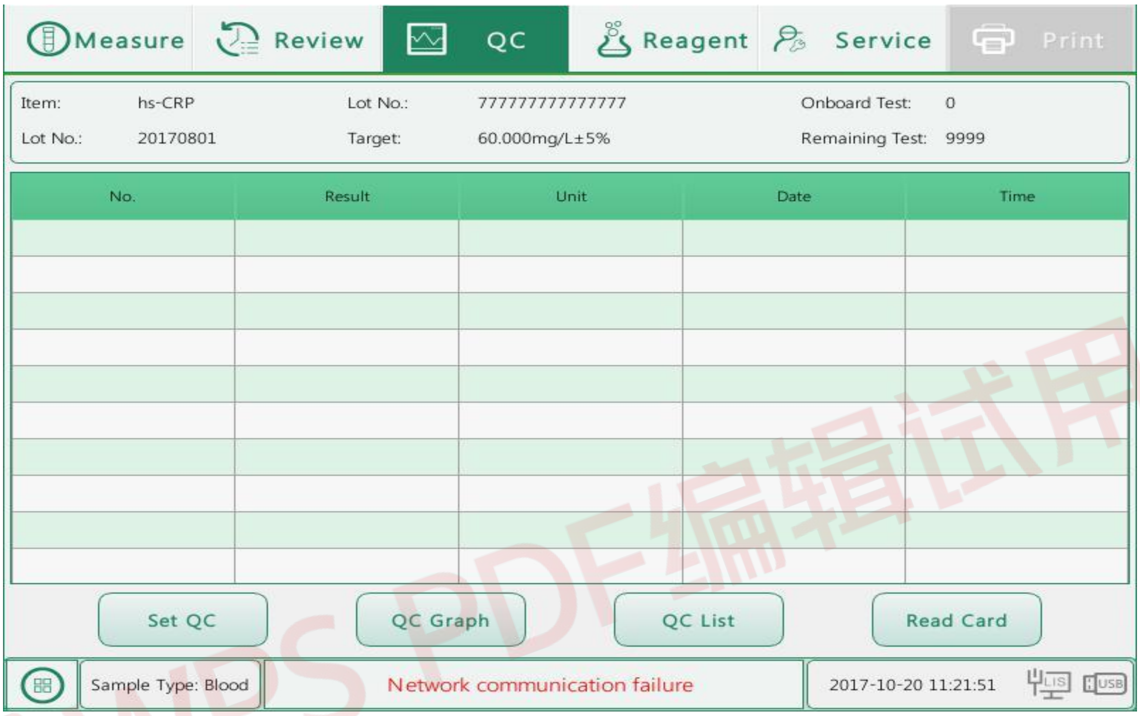


Figure 8-3

WPS PDF编辑试用

- Read Card: if the reagent card corresponding to the selected QC item is not swiped, click “Lot No.” to enter the card swiping interface to swipe the card. If the card has been swiped, the lot number of the item will be displayed at the top of the QC test interface.
- Set QC: Switch QC files in the QC setting interface according to the QC items, sample type and QC lot number which need to be tested or checked.
- QC Graph: enter the “QC Graph” interface to check the QC Graph of the current QC file.
- QC List: enter the “QC List” interface to check the QC List of the current QC file.

NOTE

- Each QC file can store up to 1000 QC results.
- When running QC analysis, the measurement interface is locked, you cannot perform other operations.

8.3. QC Graph

The QC data can be visually displayed through the QC graph. You can easily observe the distribution and deviation of the QC data, and understand the trend of the instrument deviation.

Select a QC file in the QC setting interface, click “QC Graph” to enter the QC graph interface of the selected QC file. In the “QC Graph” interface, you can click the “Set QC”, “QC Test” and “QC List” buttons at the bottom of the interface to switch to the corresponding interface.

In the QC graph, the abscissa represents the time axis, the ordinate represents the measured value and the centerline represents target value of the set item. The QC graph can display 30 QC points, count and display the Mean (average value), SD (standard deviation) and CV (coefficient of variation) of the current QC graph.

When the QC result is less than 3, no graphs are shown.

Statistics cannot be completed when QC results are less than three hours.

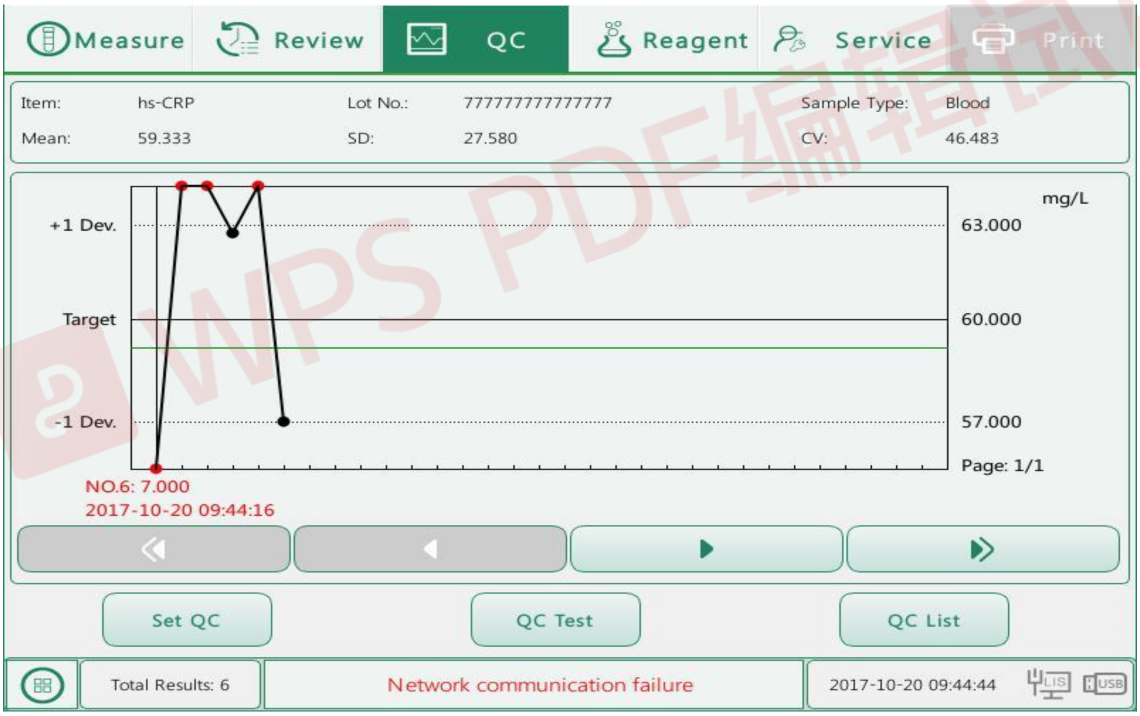


Figure 8-4

WPS PDF编辑试用

8.4. QC List

Select a QC file in the QC setting interface, click “QC List” to enter the QC list review interface of the selected QC file.

Figure 8-5

The screen displays the QC data with 10 serial numbers in a list. You can select different serial numbers consecutively by operating the scroll arrows on the right side of the screen.

- Click the “Select All” button to select all the measured QC data displayed on the current interface.
- Click the “Delete” button to delete the selected QC data.
- Click the “Print” button to print the selected QC data.
- Click the “Set QC”, “QC Test” or “QC Graph” button to switch to the corresponding interface.

8.5. Out of Control Processing

When the QC test is out of control, you should check whether or not the control is expired or contaminated, and the operation method is correct, if the problem is still unresolved, you can correct the results according to this manual, or contact our customer service department.

WPS PDF编辑试用

9. Calibrate

The calibration provides the operator with the function of calibrating the master curve, and improves the accuracy of the measurement results through the client site calibration. Master curve calibration methods are divided into 1 point, 2 point, 3 point, 4 point, 5 point, and 6 point.

1) Click the "Calibrate" button in the upper navigation bar, or enter the main menu-calibration interface, to enter the calibration measurement interface, as shown in the following figure:

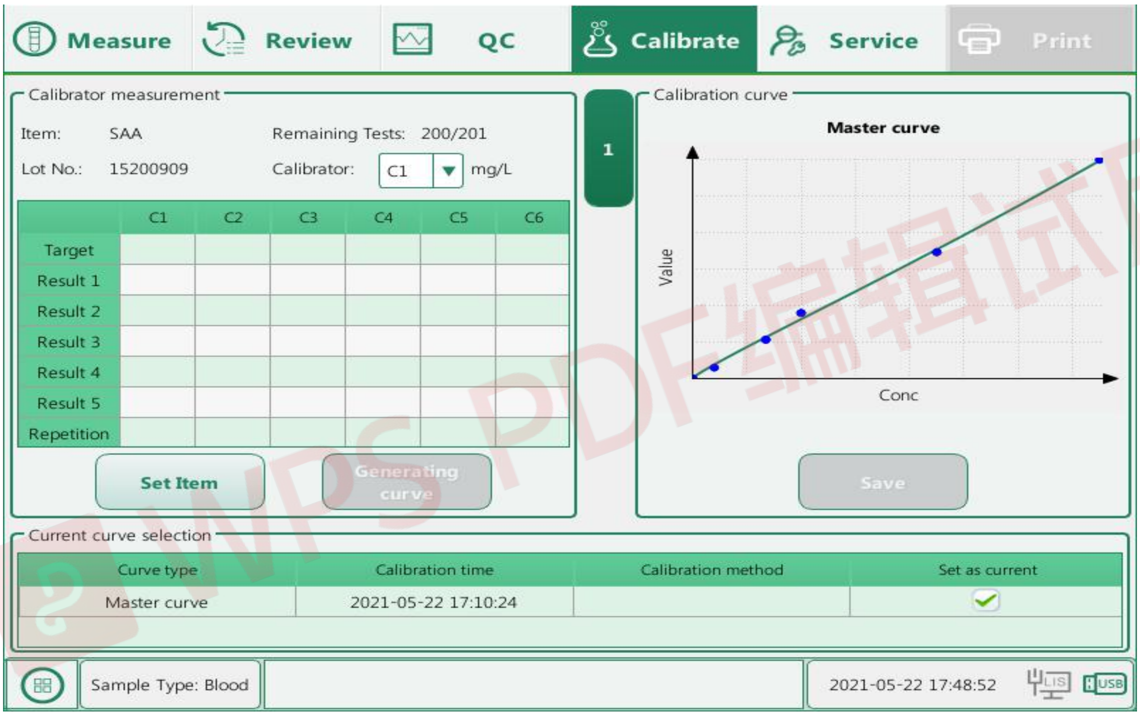


Figure 9-1

2) Select the items that need to be calibrated in the “Set Item”;

3) Take out the calibrator and enter the corresponding target value of the calibrator in the measurement area in the order from low value to high value;

4) Select the calibrator in the drop-down box of the calibrator, and measure the corresponding calibrator. It is recommended to repeat the measurement more than three times;

5) After completing the calibrator measurement, click “Generating curve”. If there is an abnormality in the calibration, there will be an abnormal prompt under the calibration curve and need to be measured again. If there is no abnormal prompt, the calibration curve is confirmed to be a normal continuous and monotonous curve. Click “Save”;

6) After saving successfully, select the calibration curve in the current curve selection area, and the calibration curve calibration is completed.

NOTE

After replacing reagent batches, replacing cuvettes, replacing sampling probes and reagent probes, and involving other system performance changes, the calibration curve needs to be re-calibrated.

9.1. Calibrator Measurement Area

Display Item, Remaining Tests, Lot No., Calibrator, calibrator measurement result lists, Set Item, and Generating curve. Among them, the calibrator is displayed in the form of a combo box. Click the drop-down button to display six options of C1, C2, C3, C4, C5, and C6. You can switch the calibrator. The calibrator measurement result list can edit the target value, result, and display the measurement result.

Click "Set Item" on the calibration interface, and the following dialog box will pop up:

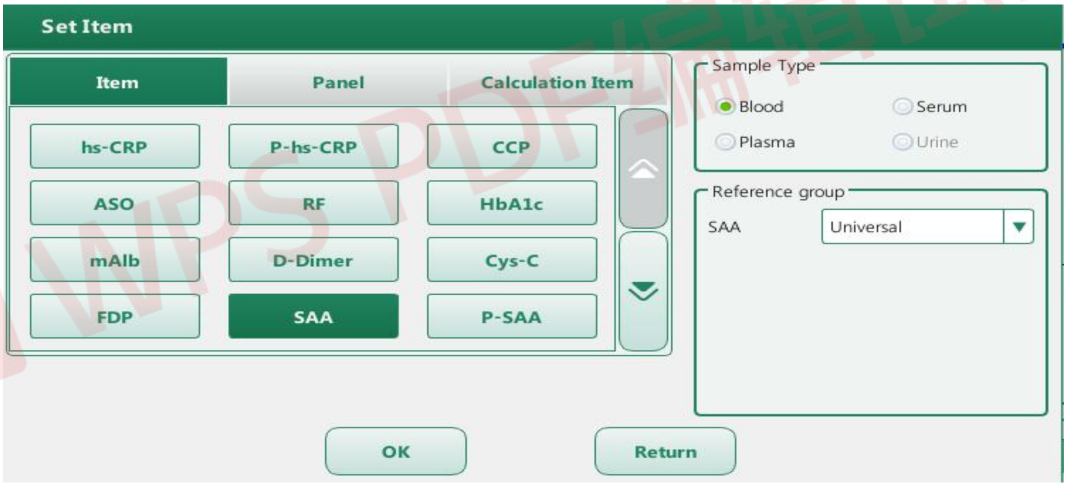


Figure 9-2

9.2. Calibration Curve Display Area

The calibration curve display area is used to display the graph of the calibration curve algorithm function in the two-dimensional coordinate axis. When the calibration curve display area is a new calibration curve, after clicking "Save", if there is no calibration curve in the current reagent batch of the item, the new calibration curve will be saved and the standard measurement result list will be cleared; after clicking "Save", if the current item has a calibration curve for the current reagent batch, delete the existing calibration curve, restore the calibration factor to the default value, save the calibration curve and clear the calibrator measurement result list.

Each item saves the calibration curve of the last ten batches of reagents.

WPS PDF编辑试用

9.3. Current Curve Selection Area

- Curve type: divided into master curve and calibration curve.
- Calibration time: The main curve is displayed as the time of swiping the card, and the calibration curve is displayed as the time of curve saving, and the format is consistent with the system date display.
- Calibration method: The master curve is empty, and the calibration curve is displayed as the number of calibration points used during calibration, including 1 point, 2 point, 3 point, 4 point, 5 point, and 6 point.
- Set as current: it is displayed by a single-selection control, and the curve currently used by the current reagent in the system is selected by default. The Measure, QC, and Calibrate interface measurement all use the curve calculation results in the use state.

WPS PDF编辑试用

10. Service and Maintenance

10.1. Overview

To maximize the performance of the analyzer, ensure its reliability and extend its life, maintenance should be performed in strict accordance with the requirements outlined in this chapter.

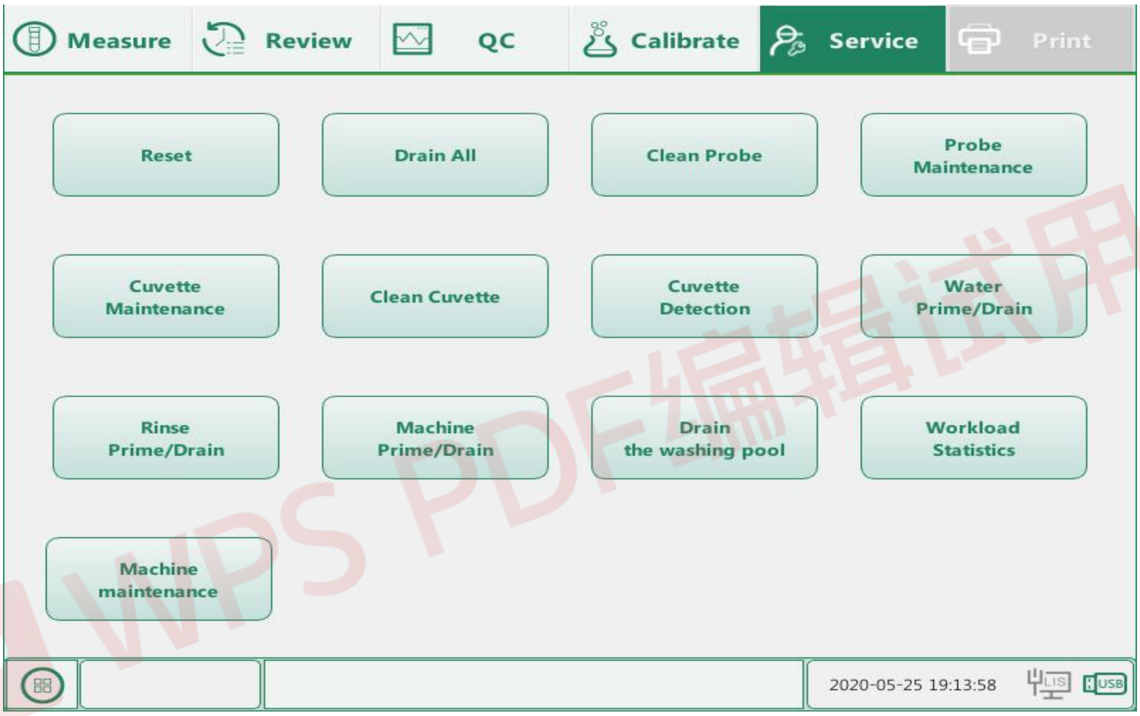


Figure 10-1

10.2. Service

10.2.1 Reset

Select “Service” in the main interface and click “Reset” button, the following prompt box pops up, select “Yes”, the analyzer will will self-test and reset.

Figure 10-2

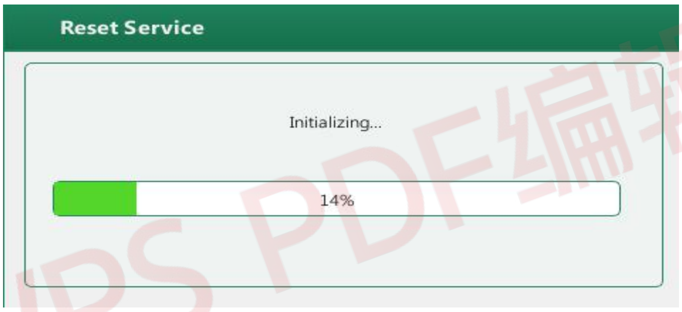


Figure 10-3

WPS PDF编辑试用

10.2.2 Drain All

If the analyzer is not used for a long time, it is recommended to perform the “Drain All” operation.

1) Select “Service” in the main interface and click “Drain All” button to enter the “Drain All” menu, as shown in the following figure.

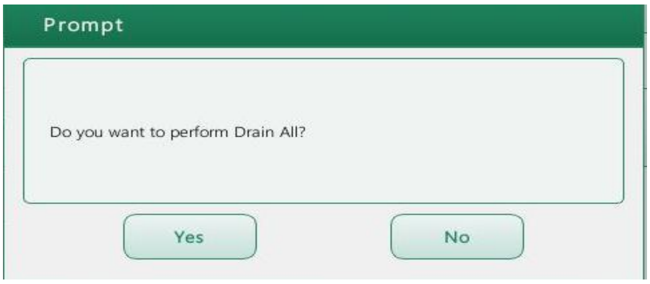


Figure 10-4

2) Click “Yes”, the analyzer will perform cuvette cleaning.

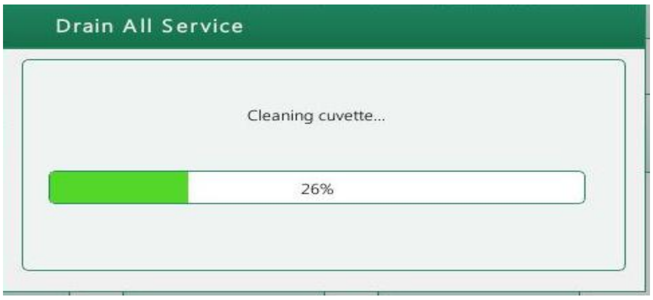


Figure 10-5

3) After cleaning the cuvette, the screen prompts as follows:

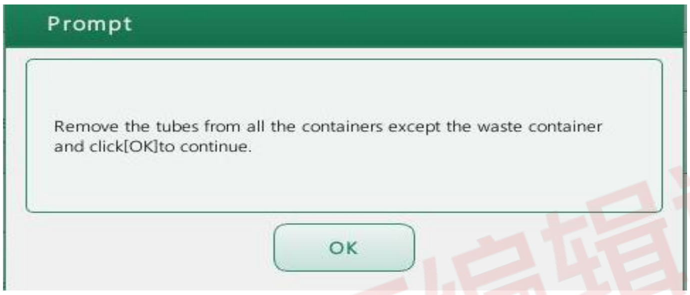


Figure 10-6

4) After the above mentioned tubes are removed, click “OK”, the analyzer will remove all the reagents in the pipeline, and the screen prompts that “Draining the fluid path…..”.

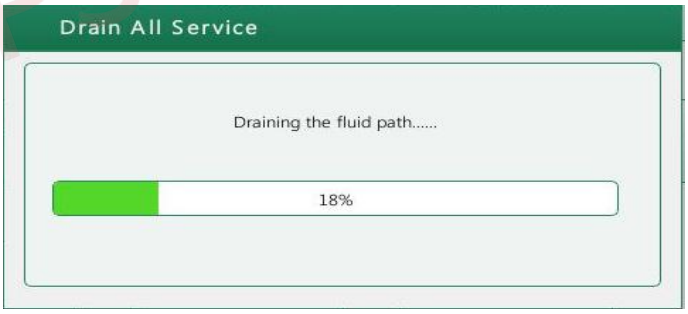


Figure 10-7

WPS PDF编辑试用

5) After the fluid path is drained, put tubes from all the containers into distilled water expect the waste container and click “OK”, the analyzer primes the distilled water into the fluid path, and the screen shows the whole machine priming progress bar.

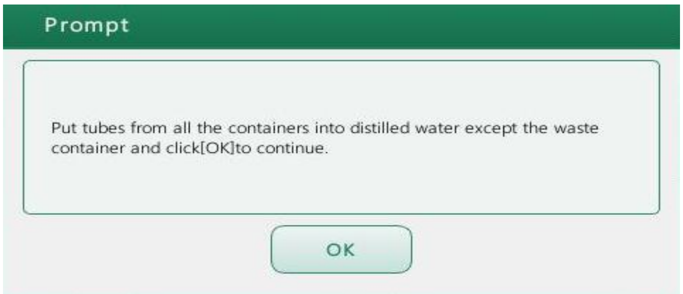


Figure 10-8

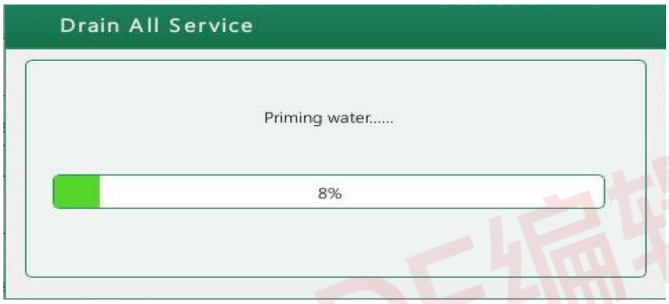


Figure 10-9

6) After completion of the priming, the screen prompts you to remove all the tubes from the distilled water and click “OK”, the analyzer drains the fluid path, and the screen shows the draining progress bar.

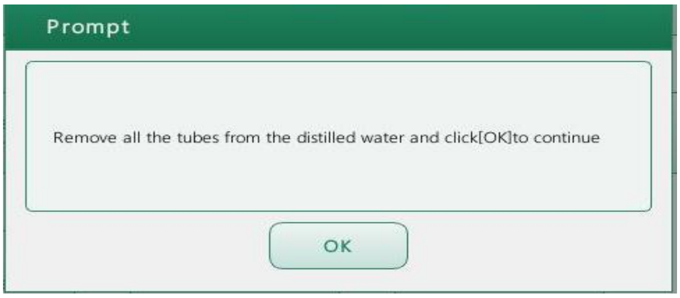
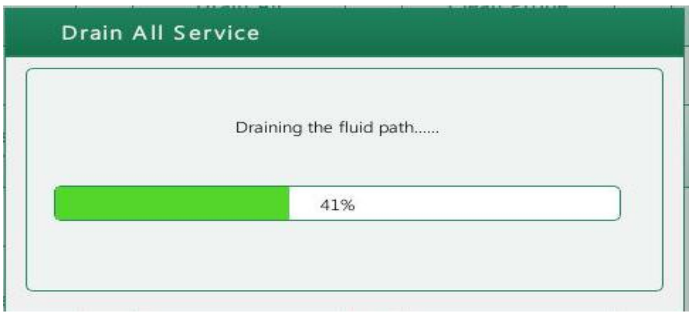


Figure 10-10



WPS PDF编辑试用

Figure 10-11

7) After draining, the screen prompts “Please turn off the power!”

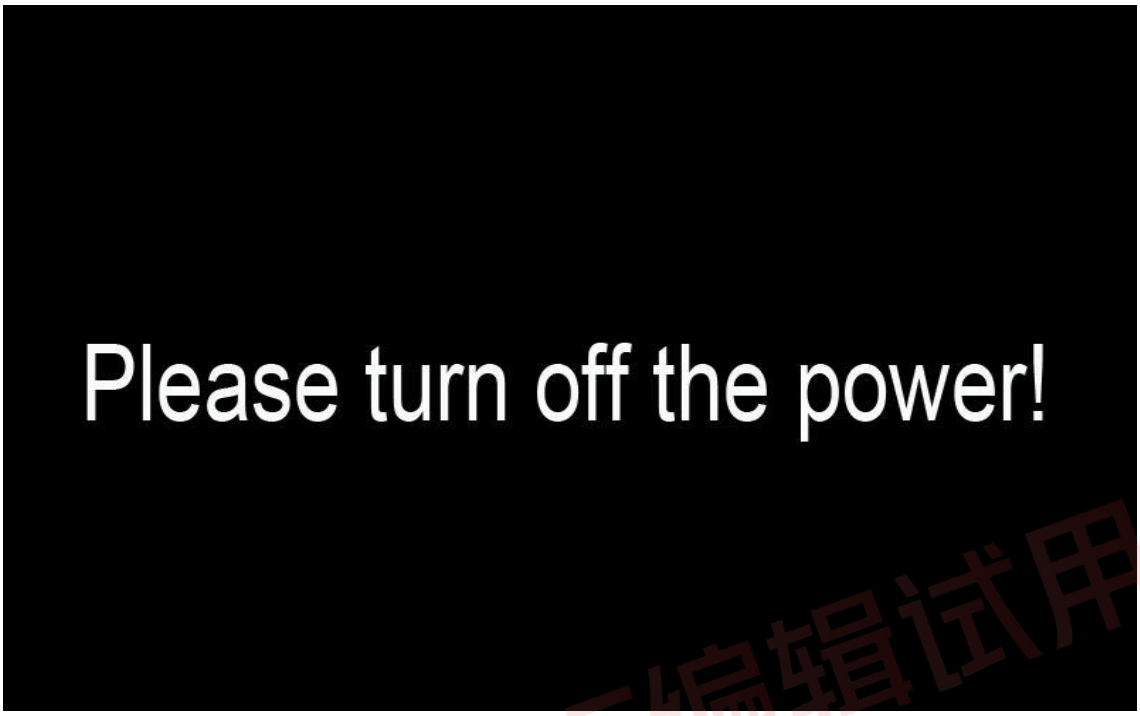


Figure 10-12

8) Turn off the power switch of the analyzer at this time, take out all the reagents in the reagent disk, and store it in accordance with the methods in the reagent instructions. Remove the fluid path tubes on the back of the analyzer, and cover the protective cap of the pipeline, take off the power cable, ground cable, sensor line and other external equipment cable, and then the analyzer can be packaged.

WPS PDF编辑试用

10.2.3 Clean Probe

1) Select “Service” in the main interface and click the “Clean Probe” button, the following prompt box pops up:

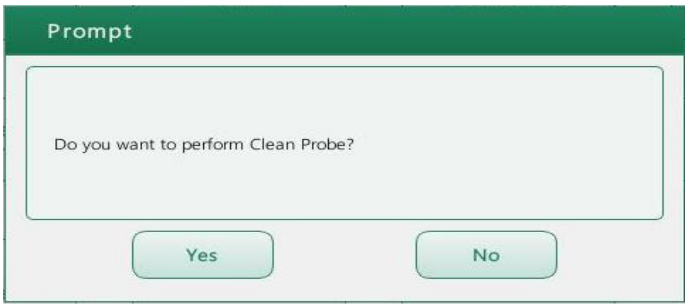


Figure 10-13

2) Select “Yes” to clean the probe, and the screen shows the cleaning progress bar.

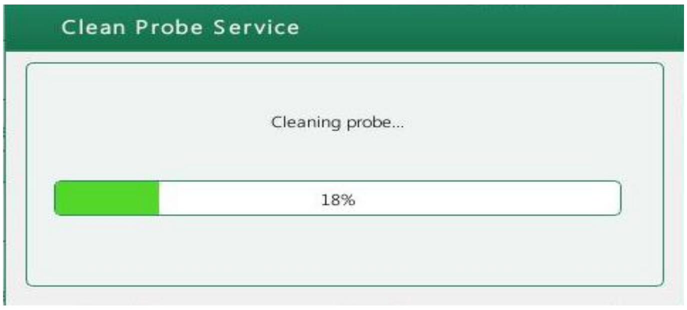


Figure 10-14

10.2.4 Probe Maintenance

1) Select “Service” in the main interface and click the “Probe Maintenance” button, the following prompt box pops up:

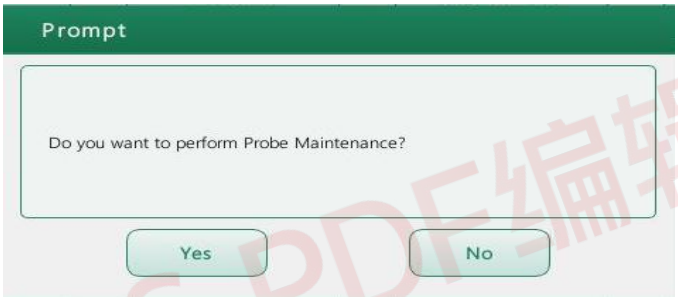


Figure 10-15

WPS PDF编辑试用

2) Click “Yes”, the analyzer automatically enters the probe maintenance sequence, the analyzer will clean the probe first.

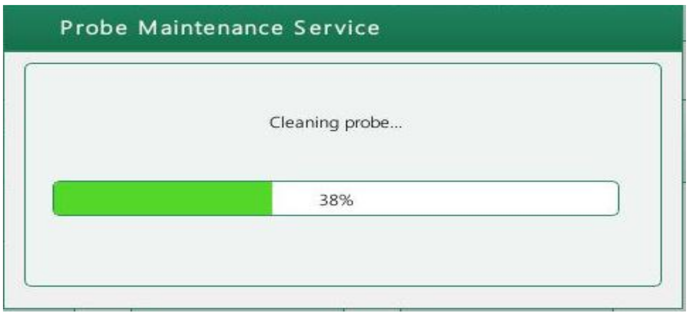


Figure 10-16

3) After cleaning, you are prompted to place the probe cleaning solution under the sample probe and then press OK.

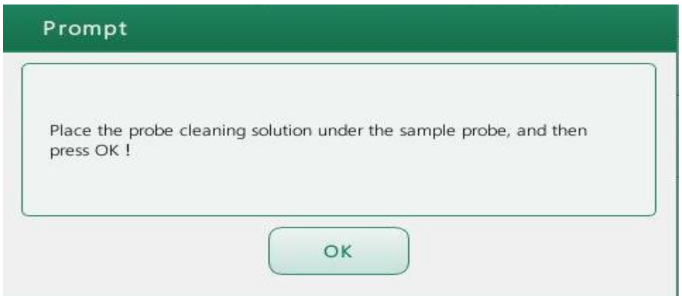


Figure 10-17

4) Place the probe cleaning solution under the sample probe and then click “OK”.

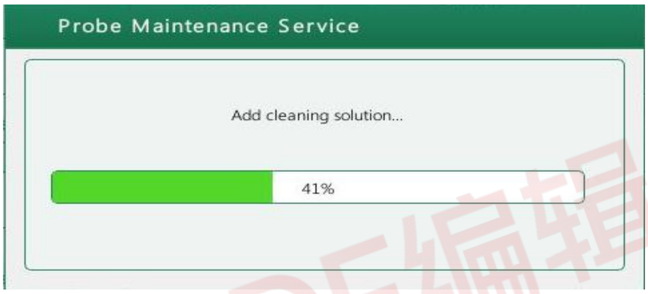


Figure 10-18

5) After adding the probe cleaning solution, the analyzer enters the time setting interface.

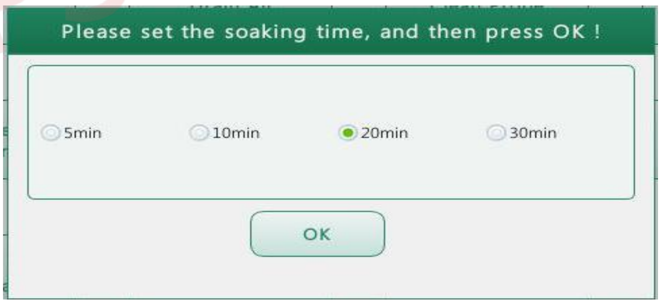


Figure 10-19

6) Click to select the corresponding time and then click “OK”.

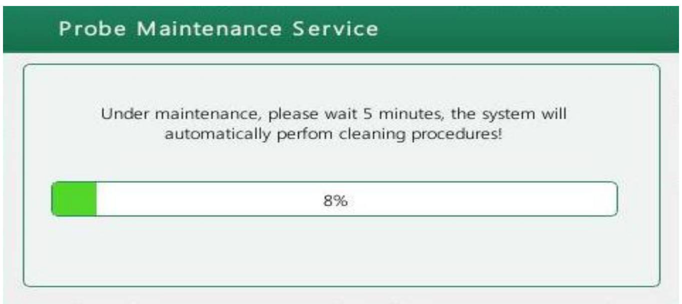


Figure 10-20

WPS PDF编辑试用

7) After the soaking time is reached, the analyzer performs cleaning automatically.

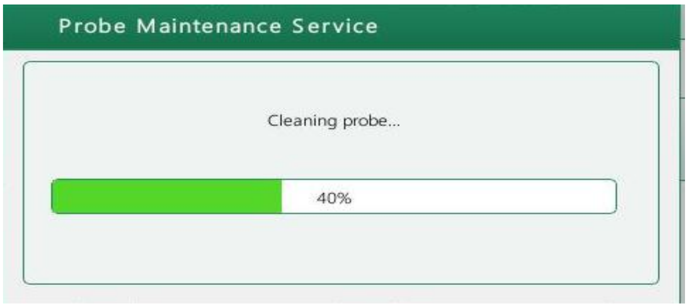


Figure 10-21

8) After cleaning, the analyzer aspirates the preparation solution of the next sample, and the screen prompts “Item switching”, the probe maintenance is finished.

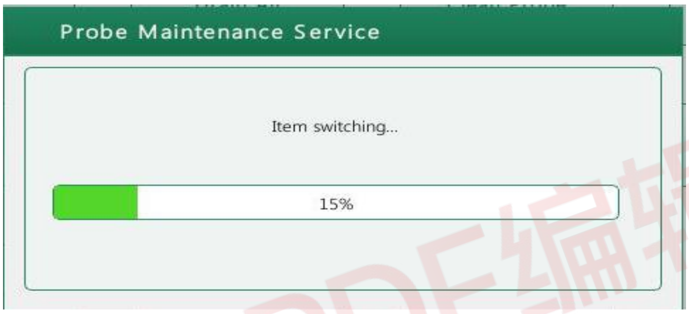


Figure 10-22

10.2.5 Cuvette Maintenance

WPS PDF编辑试用

Cuvette maintenance can maintain the cuvette and extend its service life.

1) Select “Service” in the main interface and click “Cuvette Maintenance”, the following prompt box pops up.

Figure 10-23

2) Click “Yes”, the analyzer cleans the cuvettes.

Figure 10-24

3) After cleaning, the analyzer adds rinse automatically.

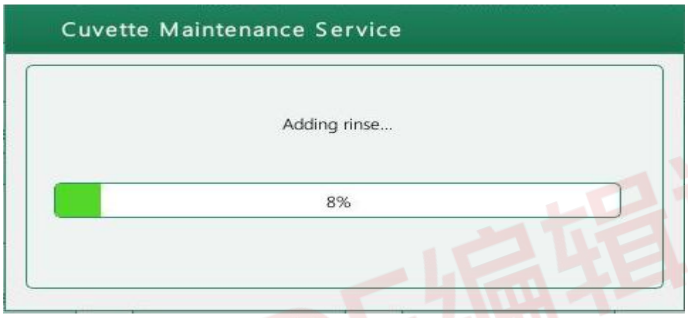


Figure 10-25

WPS PDF编辑试用

4) Set the soaking time.

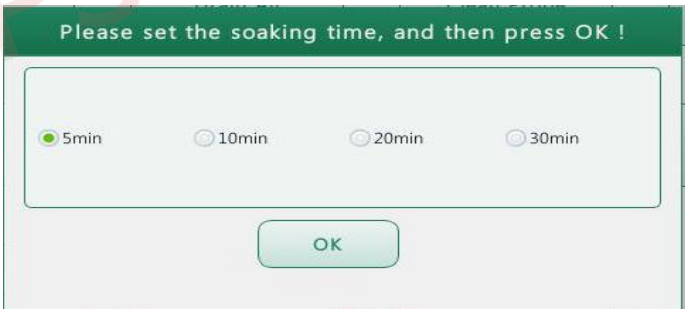


Figure 10-26

5) Select the time and click the “OK” button.

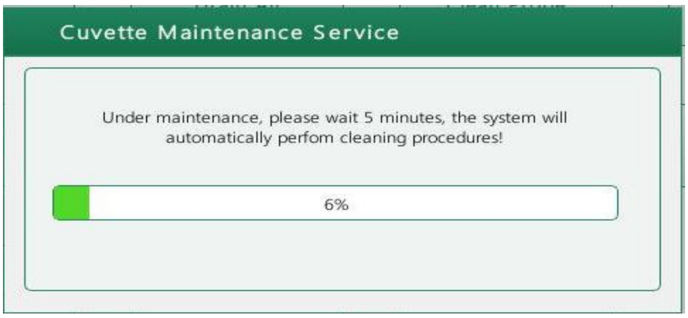


Figure 10-27

6) After soaking, the analyzer will clean the cuvette automatically.

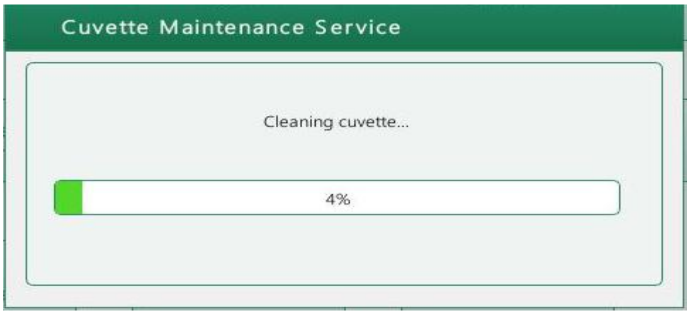


Figure 10-28

7) After the cleaning is compltete, the sample probe aspirates the preparation solution of the current selected item, and the screen shows “Item switching”.

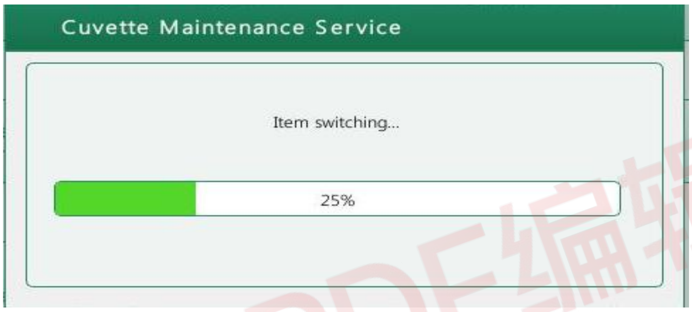


Figure 10-29

10.2.6 Clean Cuvette

1) Select “Service” in the main interface and click “Clean Cuvette”, the following prompt box pops up.

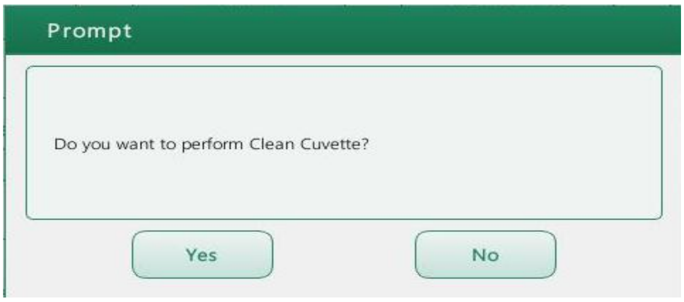


Figure 10-30

WPS PDF编辑试用

2) Click “Yes” to clean the cuvette automatically.

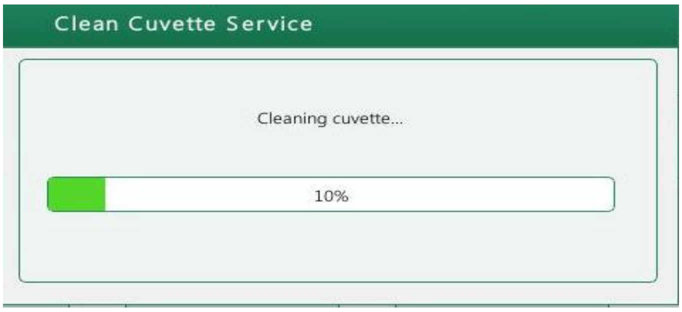


Figure 10-31

10.2.7 Cuvette Detection

1) Select “Service” in the main interface and click “Cuvette Detection”, the analyzer will prime rinse automatically.

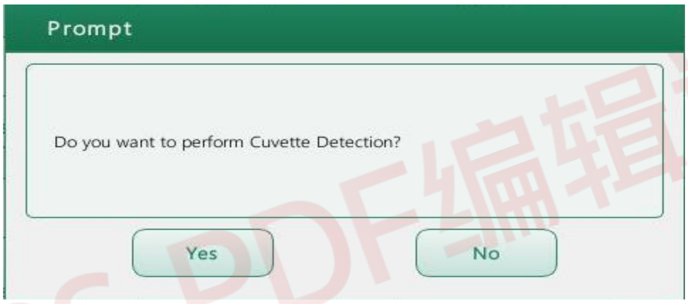


Figure 10-32

2) Click “Yes” to clean the cuvette.

Figure 10-33

WPS PDF编辑试用

3) After the cleaning is complete, the analyzer primes water for the reaction disk.

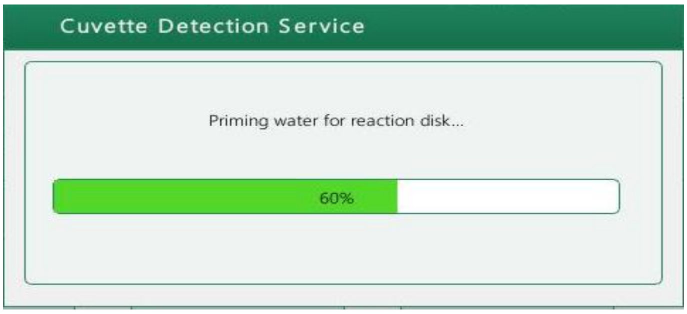


Figure 10-34

4) Detecting the cuvette.

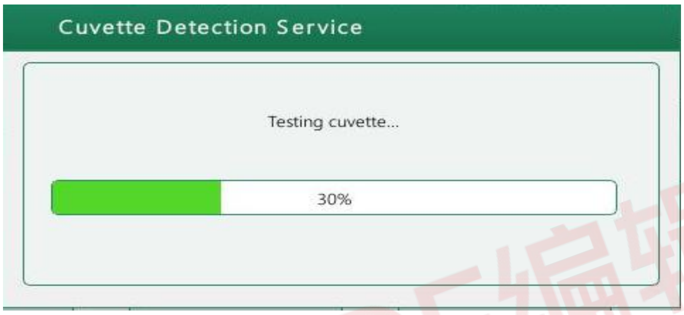


Figure 10-35

5) After the detecting is complete, the screen prompts the detection result.

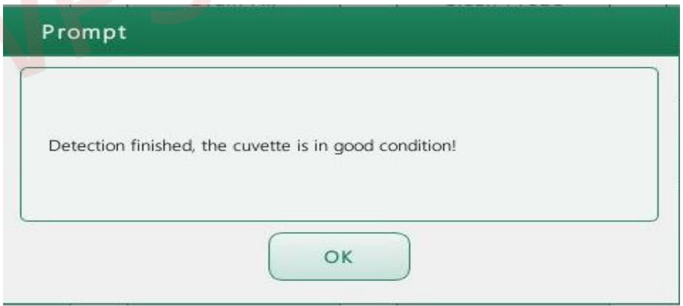


Figure 10-36

WPS PDF编辑试用

10.2.8 Water Prime/Drain

1) Select "Service" in the main interface and click "Water Prime/Drain", the following prompt box pops up, click "Yes", and then prepare the tubes according to the prompt. The tube should be inserted into the water bucket during priming and should be taken out when draining.

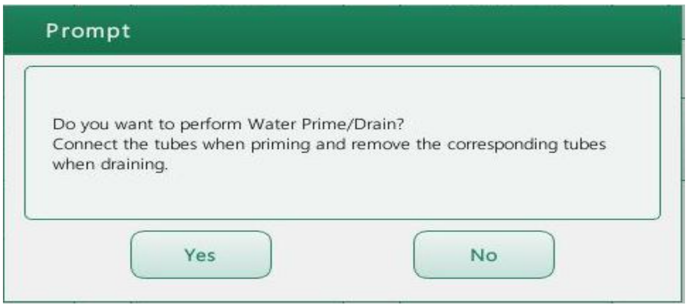


Figure 10-37

2) Click "Yes" to start the priming/draining.

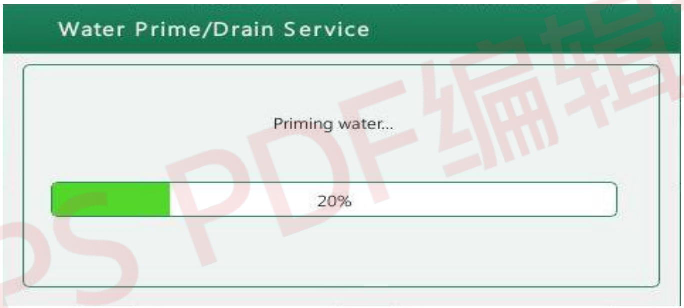


Figure 10-38

3) After the priming/draining is complete, the analyzer aspirates the prepared reagent of the currently selected item, and then the screen prompts "Item switching".

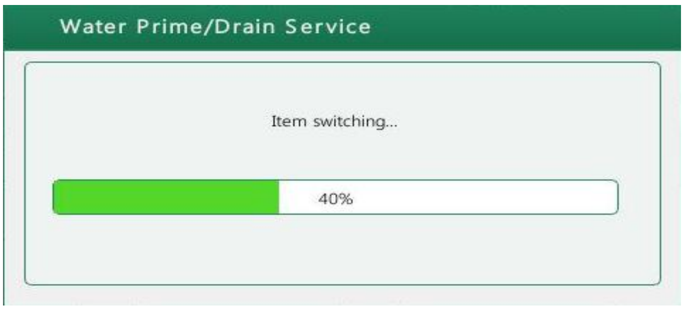


Figure 10-39

WPS PDF编辑试用

10.2.9 Rinse Prime/Drain

1) Select “Service” in the main interface and click “Rinse Prime/Drain”, the following prompt box pops up.

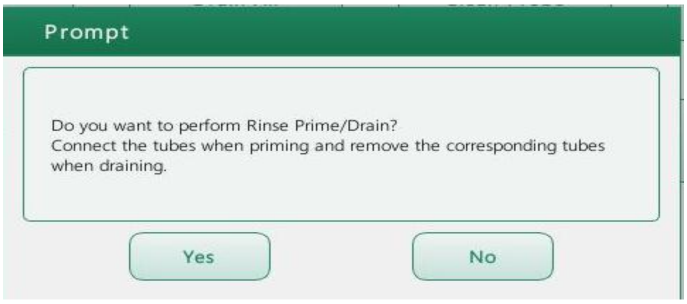


Figure 10-40

2) According to the above prompt, connect the tubes and click “Yes” to start priming rinse.

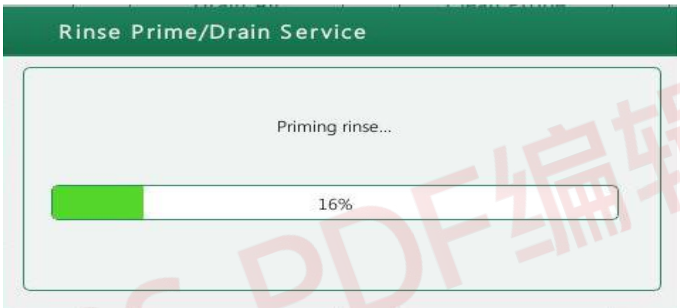


Figure 10-41

10.2.10 Machine Prime/Drain

This function is used for priming or draining the fluid path of the whole machine.

1) Click “Machine Prime/Drain”, the following prompt box pops up.

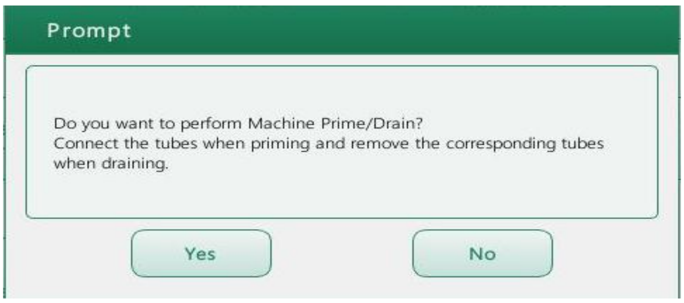


Figure 10-42

WPS PDF编辑试用

2) According to the above prompt, connect the tubes and click “Yes” to perform the operation.

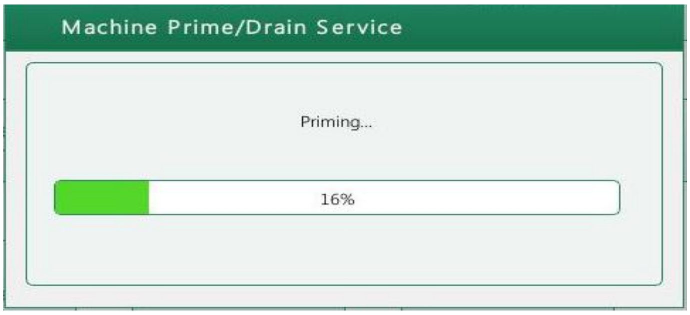


Figure 10-43

10.2.11 Drain The Washing Pool

1) Select the "Service" menu on the main interface, click "Drain the washing pool", and the following prompt box will pop up.

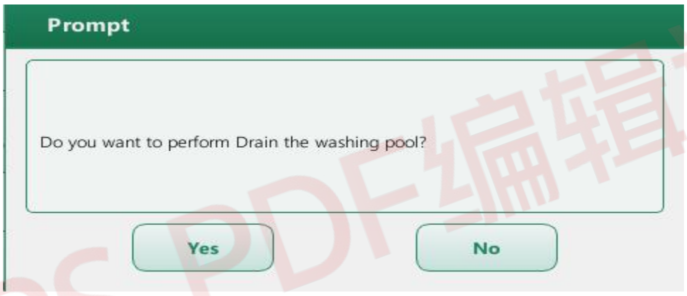


Figure 10-44

2) Click “Yes” to drain the washing pool.

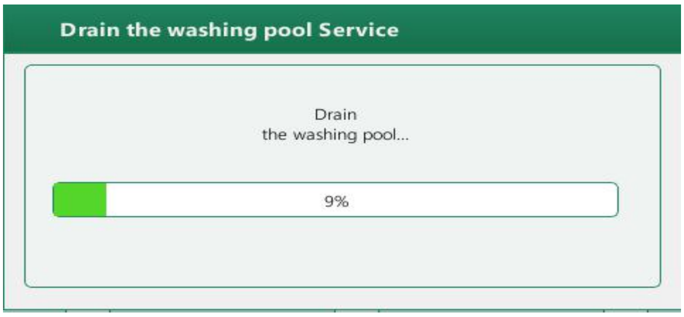


Figure 10-45

WPS PDF编辑试用

10.2.12 Workload Statistics

Click the “Workload Statistics” button to enter the workload statistics interface.

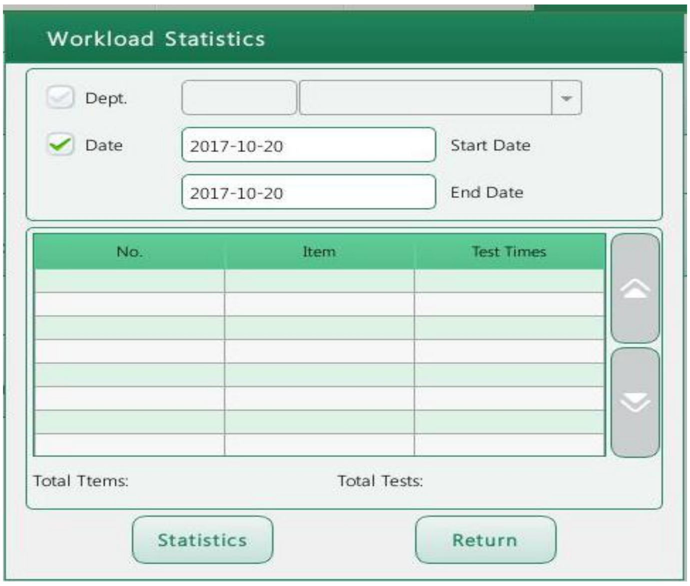


Figure 10-46

Workload statistics can be done according to the department or date by click the box in front of the corresponding option. If you choose the date mode, you need to enter the start date and the end date. Click the “Statistics” button to complete the statistics.

10.2.13 Machine Maintenance

1) Select the "Service" menu on the main interface, click "Machine maintenance", and the following prompt box will pop up.

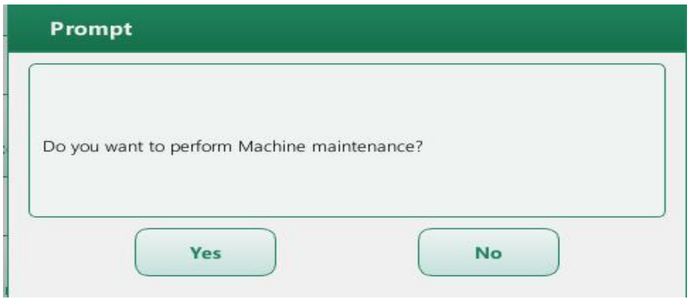


Figure 10-47

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2) Click “Yes” to start the machine maintenance and perform initialization.

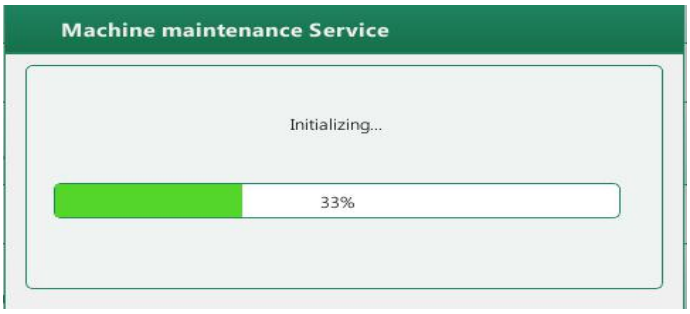

Figure 10-48

3) After the initialization is complete, start ”Clean Cuvette”.

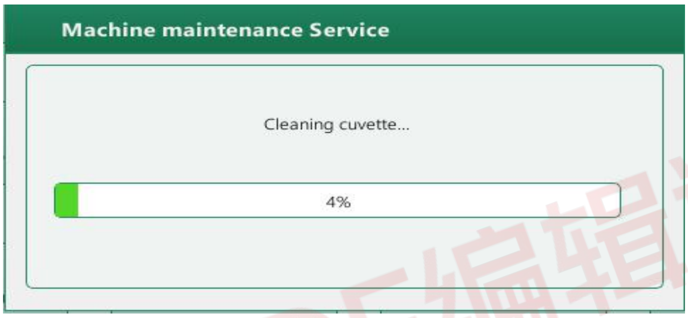

Figure 10-49

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4) After the”Clean Cuvette” is completed, start ”Adding rinse”.

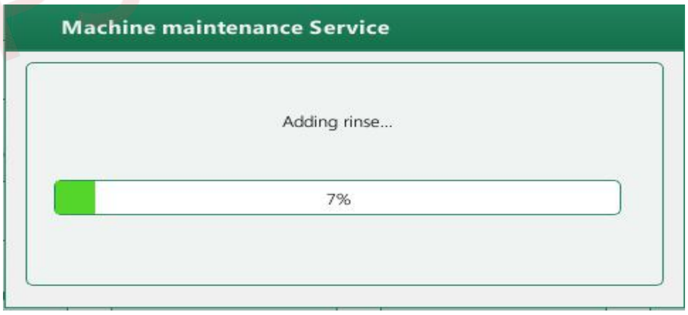

Figure 10-50

5) After the”Adding rinse” is completed, start ”Machine maintenance”.

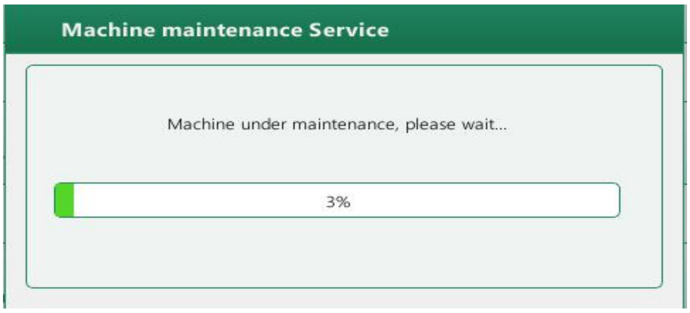

Figure 10-51

6) After the"Machine maintenance" is completed, the system will automatically perfom cleaning procedures!.

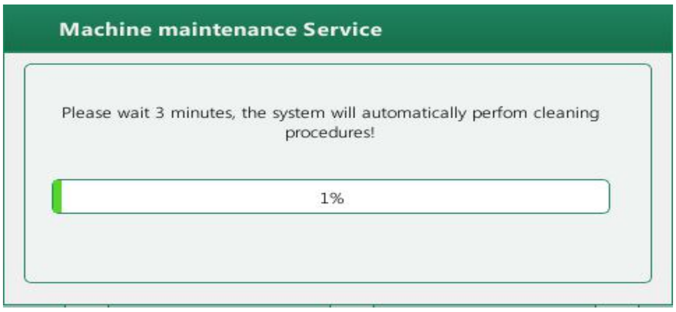

Figure 10-52

7) After the automatical cleaning is complete, start "Cleaning Cuvette".

Figure 10-53

WPS PDF编辑试用

8) After the "Cleaning Cuvette" is complete, start "Clean Probe".

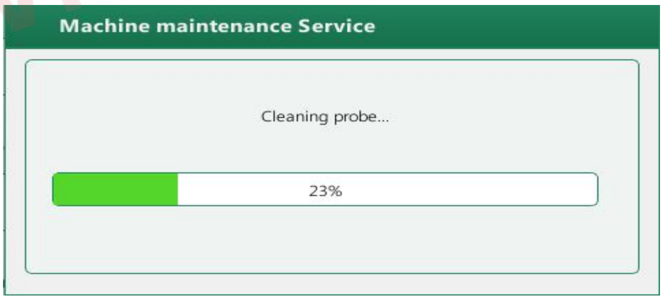

Figure 10-54

9) After the "Clean Probe" is complete, start "Item Switching".

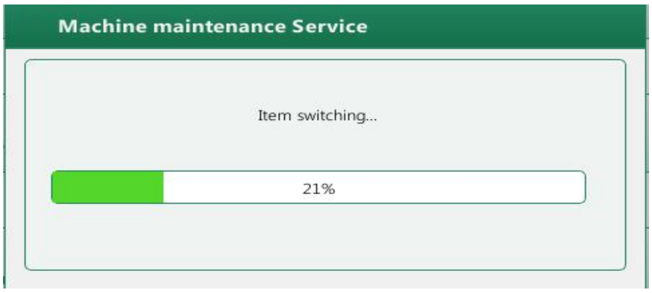

Figure 10-55

10.3. Maintenance

10.3.1 Cleaning the Instrument Surface

The analyzer countertop can easily become dirty due to spilling of reagents, reaction solution and serum, and should be cleaned promptly. The analyzer should be cleaned every day after shutdown, in accordance with the following steps:

- Cleaning: Wet a towel with cleaning solution or distilled water and wipe the analyzer countertop until all the stains are wiped clean. It is suggested to do the cleaning once a day.
- Disinfection: Wet a towel with 75% alcohol or disinfectant and wipe down the analyzer surface. After 15 minutes, wring out a clean wet towel and wipe down the countertop to remove any residual disinfectant. It is suggested to do the disinfection once a week.

NOTE

- Use neutral detergents to clean the analyzer surface, prohibited to clean the inside of the analyzer and use corrosive acid, alkali and strong volatile organic solvents such as acetone.

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The cleaning solution is chemically corrosive and protective gloves should be worn during use.

The countertop should be considered to be infectious and gloves should be worn during handling.

10.3.2 Cleaning the Probe Surface

Soak clean cotton swab in anhydrous ethanol and gently wipe the sample probe and washing probe until no foreign matter remains on the probes.

Ethanol is flammable. Make sure the analyzer is switched off when cleaning and the amount of ethanol is no more than 10ml.

All analyzer parts should be considered to be infectious and gloves should be worn during handling.

10.3.3 Fuse Replacement

The fuse must be replaced by maintenance personnel.

10.3.4 Instructions for Eliminating or Reducing Disuse

Provide the responsible person with instructions to eliminate or reduce disuse and risks involved in transportation or disposal. The instructions should contain the requirements to minimize the biohazard:

- Serum, reagents or other liquids are deemed to be infectious. If a small amount of liquids spattered onto the instrument surface, use a cotton ball dipped with “75% alcohol” to wipe it away, otherwise, contact with the surface may lead to infection and other biohazard; if a large amount of liquids splashed and penetrated into the instrument, stop using it and pull out the plug, then contact Genrui or your local distributor.

- For any carry, transfer, presentation, lending, maintenance, etc., thoroughly disinfect the instrument surface to minimize the biohazard. Once the instrument gets any collision or falls off, no matter if there's any obvious surface or internal damage, stop using it immediately and contact Genrui or your local distributor.
- If the instrument breaks down after the warranty period, ask Genrui service engineer, hospital equipment department engineer or other authorized maintenance engineer to repair it. Otherwise it may lead to risks such as electric shock. It is suggested to get in contact with Genrui before the maintenance.
- It is recommended to stop using the instrument when it reaches the retirement period, or continue the use based on an overall inspection and maintenance of Genrui.
- Only personnel trained and authorized by Genrui or its distributors can use this instrument, otherwise it may damage the protection provided by the instrument or greatly affect the test results.

10.3.5 Preventive Maintenance and Inspection

- Check whether the power cable is well connected and grounded or not before starting the instrument.
- Check whether the equipotential rod is well connected or not before starting the instrument.
- Strictly comply with the requirements described in this chapter to perform maintenance of the instrument.
- Verify the safe state of the instrument after repair.

10.4. Replaceable Device List

10.4.1 Consumables that can be replaced by users

- Printing paper
- Supporting reagents

10.4.2 Parts that need to be replaced by service engineers

- Laser source
- Fuse: specification: F6.3AL250V
- Switching power supply
- Power switch
- Cuvette assembly

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11. Troubleshooting

11.1. Overview

This chapter introduces the solutions for common faults of the analyzer. After referring to these instructions, if the problems cannot be solved or need more and detailed information, contact the customer service department of Genrui or its local distributor.

NOTE

- This operation manual is not a service manual, only provides measures that should be taken when instrument faults occur.

11.2. Common Faults and Solutions

Faults	**Possible causes**	**Suggested solutions**
Not the card for the item	Test item is not consistent with the magcard item	Check whether the item of the magcard is consistent with the input test item
The printer is out of paper	No paper or paper is not installed correctly	Replace or reinstall the paper
Buffer/antibody/diluent empty	The corresponding reagent is insufficient	Add the corresponding reagent
Rinse empty	Rinse is insufficient	Click “Rinse Prime/Drain” in the “Service” menu to add rinse
Water empty	Water is insufficient	Click “Water Prime/Drain” in the “Service” menu to add water
Waste full	Waste container is full	Pour out the waste

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12. Transportation and Storage

12.1. Transportation Requirements

The analyzer must be transported in its intact packaging according to the order contract and protected against severe shocks, vibration, rain, snow and sunlight.

12.2. Storage Conditions

The packaged analyzer should be stored at -10℃ ～ +55℃ and in a well ventilated environment with relative humidity less than 93% and without corrosive gases.

⚠CAUTION

- Do not place heavy objects on the analyzer during transportation and storage. Otherwise it may damage the analyzer.

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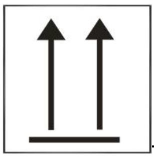
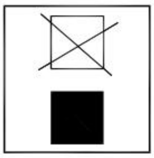
12.3. Product’s Outer Packaging Illustration

——“Fragile”: Carefully carry and place.

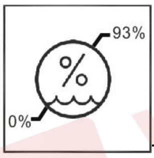


——“Up”: Upward to place and transport the product.

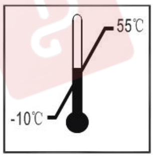
——“Rain Proof”: Protect the package from the rain.



——“No Stacking”: This package can only be in one layer.



——“Humidity Limit”: Humidity limit for transportation and storage environment.



——“Temperature Limit”: Temperature limit for transportation and storage environment.

Note: The illustrations are for reference only, subject to pictures on the outer package.

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13. Commonly-used Consumables and Ordering Method

13.1. Commonly-used Consumables

During normal use and maintenance of this analyzer, the required consumables are listed as follows:

No.	Name	Specification	Replacement cycle	Replacement method
1	Rinse	10L/bucket, 5L/bucket	Replace when runs out	Replace directly
2	Cuvette	6.6mm*6.6mm*32mm	Three months	Replace directly
3	Supporting reagents	See “List of Supporting Consumables”	Replace when runs out	Replace directly
4	Probe cleaning solution	10ml/bottle、60ml/bottle	Replace when runs out	Replace directly

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NOTE

- Direct replacement of consumables shall be performed by personnel of Genrui or qualified personnel trained by Genrui.
- The accessories for safe operation of the analyzer should be specified by Genrui, otherwise it may cause safety risks.

13.2. Ordering Method

Appendix A Specifications

A.1. Classification

According to the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices, the analyzer belongs to Other device, not in annex II and not for self-testing, not for performance evaluation.

A.2. Supporting Reagents

There are corresponding detection kits for different items.

A.3. Technical Parameters

Parameter Name	**Parameter Content**
Light source	Laser
Laser wavelength	630nm～690nm
Laser type	Class II
Laser power	≤1mW
Test method	Nephelometry
Power	≤200VA
Work type	Continuous operation equipment
Barcode device	Support barcode scanning input

A-2

A.4. Performance Indicators

The analyzer's performance should be evaluated from the following aspects: precision, accuracy, sampling accuracy and repeatability, instrument stability and so on.

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A.4.1. Precision

Under the normal working condition, calculate the coefficient of variation (CV) of the 10 test results according to formula (1), requiring CV ≤ 5%.

$$CV = \frac{s}{\bar{x}} \times 100\% \quad \text{...} (1)$$

Where:

$\bar{x}$ ----Mean value of 10 test results

$$s = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1}}$$

x_i ----Each measured result n ---- The actual number of tests

A.4.2. Accuracy

Test standard product, the deviation (B) of its mean value and the marked value should be within ±5%. The calculation formula is as follows:

$$B = \frac{\left|\bar{x} - T\right|}{T} \times 100\%$$

Where:

$\bar{x}$ ----Mean value of 5 consecutive test results

T----Nominal reference value of the reference substance

A.4.3. Sampling Accuracy and Repeatability

Test the minimum and maximum sample volume described in the instrument manual and sample volume close to 20μL, the sampling accuracy error does not exceed ± 5%, the coefficient of variation does not exceed 2%.

Test the minimum and maximum reagent volume described in the instrument manual, the sampling accuracy error does not exceed ± 5%, the coefficient of variation does not exceed 2%.

A.4.4. Stability

Under normal working condition, 4 and 8 hours later after startup, use the control material with constant value as the sample, continuously test it for 5 times (test hs-CRP, mALB and HbA1c respectively), calculate the deviation (B) of the mean value and the set value of the reference material, the deviation should be within ±5%.

A.4.5. Throughput

The maximum throughput is 60 tests / hour.

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A.5. Power Requirements

	Voltage	Frequency	Fuse
Main Unit	100-240V~	50/60Hz	F6.3AL250V

A.6. Sound Pressure

Maximal sound: 60 dBA

A.7. Environment Requirements

Working environment	Ambient temperature: 10℃-30℃ Relative humidity: ≤ 85% Atmospheric pressure: 70.0kPa-106.0kPa
Storage environment	Ambient temperature: 0℃-55℃ Relative humidity: ≤ 93%

NOTE

- Be sure to use and store the analyzer in the specified environment.

A.8. Dimension and Weight

Dimension	620mm × 520mm × 620mm (Width × Depth × Height)
Net weight	55Kg
Gross weight	97Kg

A.9. Contraindication

None.

A.10. Training

To ensure that users can properly use the analyzer and that the device will perform optimally, Genrui will send an internal dedicated service engineer or a Genrui designated distributor to the user to assist with the training.

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Appendix B Communication

Hardware condition: Connect two communicating instruments' RS-232C interface together through a RS-232C cable, or connect the instrument with one PC's COM interface. Turn on the serial port and select display by character format. The optional serial port condition for this analyzer is as follows:

Baud rate: 115200, 57600, 38400, 19200, 9600 and 4800

Parity: odd, even, none

Working status: sending, simplex

Frame sending format:

Number of bytes	Field	Content
1	Frame Header	0x02
2	Version No.	1(ASCII)
3	Instrument Type	11(ASCII)
2	Instrument No.	1(ASCII)
15	Time	0-9(ASCII)
6	No.	0-99999(ASCII)
16	Patient No.	0-999999999999999(ASCII)
3	Item No.	0--39(ASCII)
9	Result	0--9999999(ASCII)
6	Unit	0--Z(ASCII)
7	Low limit of the range	0--Z(ASCII)
7	High limit of the range	0--Z(ASCII)
1	Frame Tail	0x03

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Data sending results are as follows:

1 11 1 13 01 01 00 00 00023 000000000000441 00 00003.93 mg/L 000.00 005.00

Frame Header: (Select display by character format in the serial port)

Version No.: 1

Instrument Type: 11 indicates that the instrument type is Fully-auto Specific Protein Analyzer

Instrument No.: 1 indicates that the instrument model is PA Series

Time: 13 01 01 00 00 indicates 01 January 2013 00:00

No.: 00023 indicates the order of measurement

Patient No.: 00441 indicates that the ID test No. is 00441

Item No.: hs-CRP indicates that the test item is hs-CRP (The number of bytes is different for different test items)

Result: 003.93 displays the stored test results

Unit: mg/L indicates the chosen unit (different units have different number of bytes)

Low limit of the range: 000.00

High limit of the range: 005.00 The set normal reference range is 000.00-005.00

Frame tail: select display by character format in the serial port

If directly connected to the BS800 software of Genrui, the corresponding item numbers are as shown in the following table:

Item Abbreviation	**BS800 Item No.**
hs-CRP	0
P-hs-CRP	0
CCP	7
ASO	21
RF	22
HbA1c	4
mAlb	5
D-Dimer	2
Cys-C	3
FDP	29

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Item Abbreviation	BS800 Item No.
SAA	30
P-SAA	38
IgA	10
IgM	11
IgG	12
NGAL	31
RBP	32
TRF	9
C3	16
C4	17
PGI	33
PGII	34
β2-MG	6
H-FABP	35
Lp-PLA2	36
SAA/hs-CRP	37
P-SAA/P-hs-CRP	39
PGI/PGII	40

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Appendix C Hazardous Substances

Parts name		Hazardous substances					
		Pb	Hg	Cd	Cr(VI)	PBB	PBDE
Host	Host shell	○	○	○	○	○	○
	Host PCBA	×(1)	○	○	○	○	○
	Host sheet metal parts	○	○	○	○	○	○
	Host machining part	○	○	○	○	○	○
	Host plastic pieces	○	○	○	○	○	○
	Host metal pieces	○	○	○	○	○	○
	Host connection cable	○	○	○	○	○	○
	Host fluid path components	○	○	○	○	○	○
Accessories	Labels	○	○	○	○	○	○
	Closure assembly	○	○	○	○	○	○
	Maintenance tools	○	○	○	○	○	○
	Liquid inlet adapter assembly	○	○	○	○	○	○
	Test tube rack	○	○	○	○	○	○
Package	Packaging materials	○	○	○	○	○	○

○: means the content of the hazardous substance in all homogeneous materials of the part is in the limited requirement according to the standard of SJ/T 11363-2006.

×: means the content of the hazardous substance in at least one of the homogeneous materials of the part is beyond the limited requirement according to the standard of SJ/T 11363-2006.

(1): some parts of the circuit board used lead solder during processing.

Notice: the product marked with "×" is because there has no other technologies or parts to be replaced at present stage, under normal use conditions, leak and mutation will not occur in 5 years, and it will not cause environment pollution or harm to people and property.

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