Test Cartridges

Parameter	· BG3 · BG3-N	· BG4 · BG4-N	· BG5 · BG5-N	· BG6 · BG6-N	· BG7 · BG7-N	· BG8 · BG8-N	· BG10 · BG10-N	· BE4	· BE5	· BE6
pH	●	●	●	●	●	●	●		●	●
pO_2	●	●	●	●	●	●	●			
pCO_2	●	●	●	●	●	●	●			
K^+					●	●	●	●	●	●
Na^+					●	●	●	●	●	●
Cl^-					●	●	●	●	●	●
Ca^{2+}					●	●	●	●	●	●
Hct				●		●	●			●
Glu			●	●			●			
Lac		●	●	●			●			
tCO_2*	●	●	●	●	●	●	●	●	●	●
cHgb*	●	●	●	●	●	●	●	●	●	●
$cHCO_3^-$*	●	●	●	●	●	●	●	●	●	●
BE(ecf)*	●	●	●	●	●	●	●	●	●	●
BE(b)*	●	●	●	●	●	●	●	●	●	●
cSO_2*	●	●	●	●	●	●	●	●	●	●
AG*	●	●	●	●	●	●	●	●	●	●

** Calculated parameter*

Measured Parameter

Parameter	
Na^+	pCO_2
K^+	pO_2
Cl^-	Hct
Ca^{2+}	Glu
pH	Lac
Li #	Mg #
tCO_2 #	.....

 # Under development

Calculated Parameter		
pH(T)	cH^+	$cH^+(T)$
$pCO_2(T)$	$cHCO_3$	$cBase(B)_e$
$cBase(Ecf)_c$	$cBase(Ecf,ox)_c$ #	$cHCO_3^-(P, st)_e$ #
$cBase(B,ox)_e$ #	$ctCO_2(B)$	$ctCO_2(P)$
$pO_2(T)$	$pO_2(A)$	$pO_2(A\text{-}a)$
$pO_2(a/A)$	$ctO_2(B)$	RI
cHgb	$pO_2(a)/FO_2(I)$ #	$pO_2(a/A,T)$
$pO_2(A\text{-}a,T)$ #	$pO_2(a,T)/FO_2(I)$ #	RI(T)
$cCa^{2+}(7.4)$	Anion $Gap(K^+)_c$	cSO_2
AG	$FO_2(I)$ #	.....

 # Under development

seamaty

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seamaty

SG1

Blood Gas & Electrolyte Analyzer

A handheld blood analyzer that delivers lab-quality, diagnostic results in minutes.

www.seamaty.com

CE ISO

Product features

Easy to use

Testing can be performed in 3 simple steps at the patient's side with only 2 or 3 drops of whole blood.

Handheld portability

Lightweight with build-in battery allowing diagnosis at the point of care, patient side, out in the field or exam room.

Fast results

Get accurate results in 4 minutes at the patient's side to enable rapid decision-making, and optimize patient-care.

Multi-parameter cartridge

Single-use test cartridges a broad menu of tests on a single, portable platform. Each test card has a unique combination of biosensors to suit a wide range of clinical needs.

Use Cases

Emergency Treatment

ICU

Oncology

Anesthesiology Department

Gynecology and Obstetrics

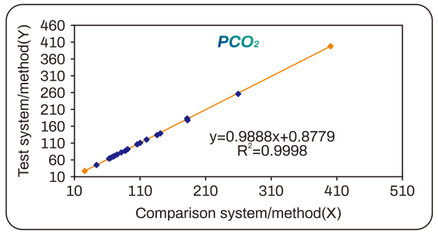
Clinical Laboratory

Test Cartridges

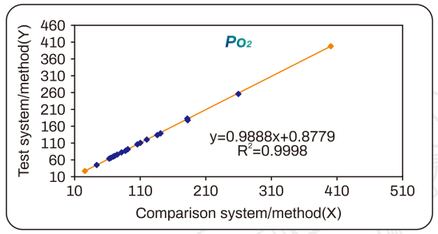
Sample	Whole blood / Capillary
Test Time	50s
Display	4.3 IPS touch screen
Weight	600g
Battery	3.7V, 5000mAh Up to 55 samples in a row

Sample volume	100 µl
Connectors	Type c
Printer	Built-in thermal printer
Connection	WIFI, Direction LIS (HL7)
Operating temperature	Temperature: 5 - 32℃; Relative humidity ≤85%;

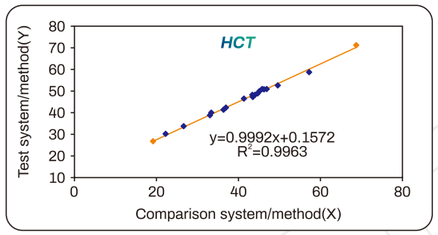
Reagent performance analysis



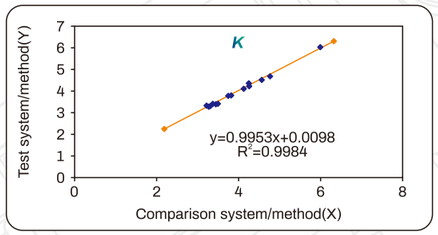
Abbott



Abbott



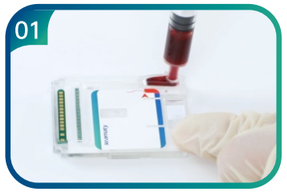
Abbott



Abbott

Easy 3 steps operation

Regular Test Cartridge



01

Add sample

Add 2 or 3 drops of whole blood into cartridge

02

Insert cartridge

Insert the cartridge into the analyzer

03

Read result

Read the test report in 4 minutes

Auto Aspiration Cartridge

01

Insert syringe

Flat insert the syringe into the fill port of test cartridge

02

Insert cartridge

Insert cartridge into the analyzer

03

Read result

Read the test report in 4 minutes

结业证书

CERTIFICATE

We, Seamaty Diagnostic Co., Ltd.

Addressing at Floor 11, Building H, Zhengtong Electronics Industrial Park, No. 3 Yutang Community, Yutang Street, Guangming District, Shenzhen City, China do hereby acknowledge to

POHILCO IRINA

From **Sanmedico SRL** has attended training of **Blood Gas & Electrolyte Analyzer SG1** on April 7, 2026.

The certificate is valid until April 6, 2027

seamaty 斯马特

Seamaty Diagnostic Co.. Ltd. April 7, 2026

SG1

Blood gas & electrolyte analyzer

User Manual

Chengdu Seamaty Technology Co.,Ltd

Contents

Notes

Dear user:

Welcome to Seamaty Diagnostic Co., Ltd. Handheld Device SG1 Blood gas & electrolyte analyzer !

We are honored that the Blood gas & electrolyte analyzer (hereinafter referred to as the analyzer) can gain your trust. In order to give you a general understanding of our products, we have configured the instruction manual for you, including :

The analyzer features, dimensions, usage, instructions, maintenance, packaging, storage, transportation, etc. It is an essential guide for you to use this instrument. For the arrangement of the data, we strive to be comprehensive and easy to understand, so that you can better understand the relevant knowledge of the instrument. Before use, please read the instruction manual carefully, I believe it will be of great help to your effective use of the analyzer. The instruction manual is the instruction for using the analyzer. In order to ensure the good operation of the analyzer and the accurate and reliable test results, please strictly abide by the " Cautions " , " Tips " and " Warnings " in the instruction manual .

How to use the manual correctly

scope of application of this manual:

1. Users (personnel) who have received operation training from Seamaty Diagnostic Co., Ltd;

2. Users (personnel) who have received operation training from authorized dealers of Seamaty Diagnostic Co., Ltd

In principle, the instruction manual was correct at the time of publication. In the process of use, if you find any errors or omissions in this manual, please call or write to us in time to inquire. See the last page of the instruction manual for phone numbers and addresses.

In order to improve the performance and reliability of the components and the whole machine, we will make some real-time changes to the hardware or software , which may cause the changes to be out of sync. The company reserves the right to revise the instruction manual and maintain the software version. without notice!

Without the written consent of the company, no individual or organization may copy, modify and translate the contents of the manual.

The company has the final right to interpret the contents of this instruction manual.

The illustrations used in the instruction manual are examples and may differ from the actual product. If there is any difference, the actual product shall prevail.

Please ensure that the analyzer is used under the conditions specified in the instruction manual, otherwise the analyzer may not work properly and the test results may be unreliable.

If the equipment is used in a manner not specified by the company, the protection provided by the equipment may be damaged.

Warning and safety reminder signs

warning icon	name	meaning
	warning	You should know how to avoid possible injury to operators, and please refer to the label in the manual
	Caution	Important information you should know to avoid possible damage to your equipment
	Watch your hands	When opening and closing the compartment door, pay attention to prevent hand clamping
	Note	Important information during operation
	Biological risks	Contaminated plasma, serum and other specimens may be touched during operation , please pay attention to protection
	Protective earthing	protective earth terminal

How to use SG1 blood gas and electrolyte analyzer correctly

Before use, it is recommended that you do the following:

1. First carefully check whether the actual configuration of the instrument is consistent with the packing list. If there is any objection, please contact our salesperson or distributor.

2. In order not to affect your future service, please fill in the service guarantee form carefully, and send the product warranty card (receipt) back to our company as soon as possible (or scan the email and send it back to our company: E-mail: info@seamaty.com) .

3. Please read the random documents carefully and keep them properly.

 **warning:**

The analyzer should avoid working in a humid environment containing corrosive gases.

When the analyzer emits peculiar smell or smoke during use, cut off the power supply and unplug the power cord in time, and notify the manufacturer or agent for maintenance.

Operators should avoid contact with the electronics within the analyzer , and only qualified personnel should perform repairs.

Operators should wear protective gloves, masks, and work clothes.

It is the user's responsibility to ensure the electromagnetic compatibility environment of the analyzer equipment so that the equipment can work properly.

This analyzer complies with the emission and immunity requirements of this equipment in GB/T 18268 .

This analyzer is designed and tested according to Class B equipment in GB 4824.

the analyzer near strong radiation sources (such as unshielded radio frequency sources) , otherwise it may interfere with the normal operation of the equipment.

 **Caution：**

The working environment of the analyzer should be ventilated, avoid strong electromagnetic field interference and dust pollution, and the instrument should be placed on a stable workbench.

Do not damage the power cord, hold the plug when unplugging, do not pull on the power cord.

Do not put water containers or small metal objects on the analyzer to prevent water or metal objects from falling into the instrument, causing a short circuit and damaging the instrument.

The analyzer should use the original power adapter and ensure good grounding.

Do not use the analyzer in a location where it is difficult to disconnect the switch.

See the label on the back of the instrument for the date of manufacture of the analyzer.

The reagent cards referred to in this manual are all Plitix reagent cards that are matched with SG1 as an example.

 **Biological risks :**

In accordance with the requirements of standard laboratory practice, considering the potential biological risk of blood samples, all samples, quality controls, related containers and used reagent cards should be handled according to the corresponding biosafety level.

If you stop using the analyzer or need to re-transport, please remove the reagent card from the instrument and clean the analyzer according to the instructions in Chapter 5 to prevent biological hazards.

Quality assurance

SG1 Blood Gas and Electrolyte Analyzer, considering the influence of environment and unexpected factors, if the user uses it properly, it is recommended that the user use it for 5 years.

From the date of receipt of the product, the company promises to provide analyzer users with a 24 -month free warranty service (excluding consumables), except in the following cases:

analyzer normally or not using the standard supporting consumables in strict accordance with the instruction manual ;

man-made injury;

Disassemble the analyzer without the permission of the company.

The above warranty service is exclusive to the initial installation user of the analyzer, and it is invalid to transfer or share the warranty service with others.

observe safety measures

For safe and efficient use of the analyzer, please observe the following precautions:

1. Avoid equipment failure

The installation environment of the analyzer must meet the installation environment requirements in the instruction manual.

2. Prevent electric shock

Without the authorization of our company, please do not open the analyzer casing by yourself to prevent liquid splashing into the analyzer. In order to prevent safety accidents such as electric shock, if the liquid accidentally enters the analyzer, please contact the company's after-sales personnel in time before using it. Please check whether the power cord is in good condition before using it. Do not use damaged power cords to prevent electric shock.

3. Prevent pollution

Protective gloves must be worn during biochemical testing operations, and direct contact with the sample to be tested without wearing protective gloves poses a potential risk of biological infection. There are also potential biosafety issues for post-test discs that have not been biosafely processed. In case of direct skin contact, wash and disinfect the contact area immediately and consult a doctor.

4. Please strictly follow the operation methods and precautions in the reagent card manual.

Chapter1 Instrument Structural Features

1.1 Appearance of the instrument

The front profile is shown in figure1-1.

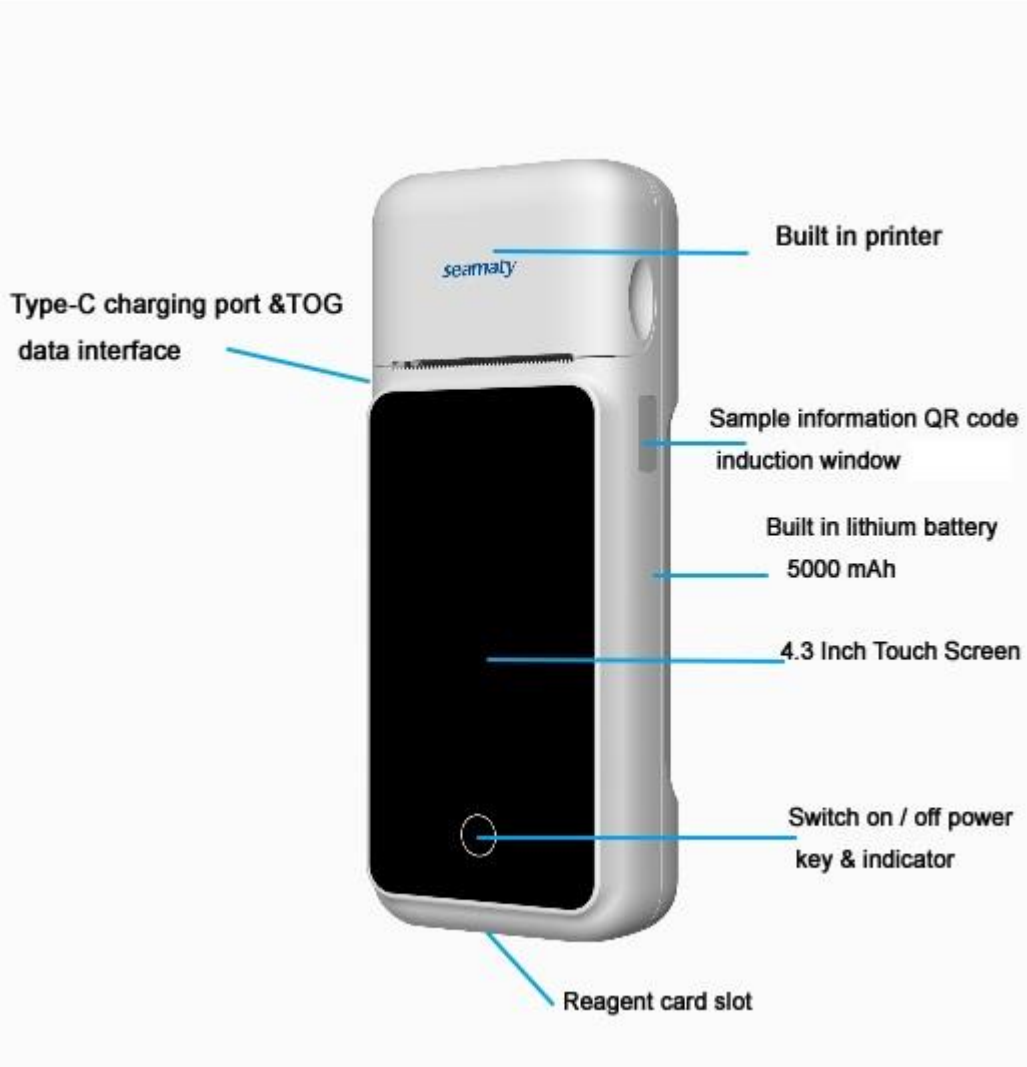


Figure 1-1

1、Built-in printer :Thermal printer: print specification:57*40mm

2、USB Interfaces：Type-C can be charged，support the transfer of OTG

3、Sample information QR code sensing window:(optional)

4、Built-in battery：5000mAh lithium battery

5、Touch screen：4.3 inch IPS HD touch screen

6、Power button: long press 2s on/off button, power on state,short press to return.

7、Reagent card slot：Test reagent card slot.

1.2 Basic introduction

Product Name: Blood gas & electrolyte analyzer

Specification model: SG1

Dimensions: 220 mm(L)* 90 mm(W)* 52 mm

Net weight:0.9 kg

The SG1 Blood gas & electrolyte analyzer is easy to operate. The operator only needs to collect a whole blood sample，add90-120μl to a reagent card，insert the card into the reagent card slot of the Analyzer，

and the test is automatically completed.Once the Analysis is complete, the results are automatically displayed and can be printed out。

The SG1 Blood gas & electrolyte analyzer is equipped with a type-C port for charging the instrument or connecting a HUB to an external printer or device such ad a mouse,keyboard,USB stick,etc.

1.3 Detection principle

SG1 Blood gas & electrolyte analyzer is a kind of analyzer based on microprocessor analysis and calculation, so as to determine the concentration of ions and other substances in the sample, in order to achieve the purpose of detection, it is recommended to use together with the matching reagent card. The product performs blood gas electrolyte analysis on the human body by examining patient samples.

SG1 Blood gas & electrolyte analyzer detection principle is： add test sample in the reagent card beforehand， insert the reagent card containing the sample into the analyzer， Mechanical drive system controlled by microprocessor electrical operation, in turn reagent package calibration fluid at a constant speed and the sample under test after extrusion through the "capillary reaction chamber" with an electrode in electrochemical reaction and generate an electric current, voltage and conductance change, system by detecting the changes, and through the analysis of microprocessor to determine the concentration of ionic substances such as in the sample, To achieve the purpose of detection. After the analysis, the results are automatically displayed and printed。

1.4 Product structure and composition

The Blood gas & electrolyte analyzer consists of main frame, power adapter and software(release version:V1).The main frame includes: whole shell, core component, constant temperature control component, QR code scanning acquisition component, Electrochemical detection component, printer component, LCD capacitor display + touch panel, lithium battery.

The analyzer has hand-held structure, small size, light weight, easy to carry by hand and convenient transportation. The analyzer components have the following characteristics:：

- A plastic shell for the whole machine
- Two microprocessors for instrument control and test calculation respectively (Core component, QR code scanning acquisition component)
- A thermal printer that prints results (print components)
- 4.3-inch IPS HD touch Screen (display)
- Has multiple choice capabilities related to testing and result processing (operating software)As shown in figure1-2

Figure 1-2

1.5 Product Features

- 4.3-inch IPS HD touch screen, Linux operating system, multiple language selection.
- Fifteen independent channels were tested without cross contamination.
- Test method: resistance method, current method and conductance method。
- Venous whole blood or arterial whole blood samples can be analyzed.
- Sample information storage meets customer information storage requirements。
- Support external mouse, keyboard, printer (based on USB)。
- Built-in thermal printer.

1.6 Intended use

This product is used for quantitative determination of electrolyte content, blood gas parameters and metabolite content in blood and body fluid in vitro.

This product is for professional use only！

1.7 Analyte

K+、Na+、Cl-、Ca2+、pH、pCO2、pO2、Hct、Glu、Lac

1.8 Electromagnetic Compatibility Statement

- The electrical safety of the product complies with EN61010-1:2010 <Safety requirements for electrical quipment for measurement,control,and laboratory use-Part 1: General requirement> and EN61010-2-101:2017 <Safety requirements for electrical quipment for measurement,control,and laboratory use-Part 1: General requirement Part 9: Particular requirements for Automatic and semi-automatic equipment for Analytical and other Purposes Used in Laboratories>.
- The environmental test of this product meets the requirements of GB/T14710-2009 <Environmental Requirements and Test Methods for Medical Electrical Equipment>.
- This product complies with YY0648-2008 <Safety requirements for electrical quipment for measurement,control,and laboratory use-Part 1: General requirement>Part 2-101: Special requirements for in vitro diagnostic (IVD) medical equipment。
- The electromagnetic compatibility test of this product meets EN61326-2-6:2013 <Electrical equipment for measurement,control and laboratory use-EMC requirements - part 26: Particular requirements-In vitro diagnostic(IVD)medical equipment and EN61326-1:2013 <Electrical equipment for measurement,control and laboratory use-EMC requirements-Part 1: General requirement>.
- The product meets the requirements of Group 1 class B devices in <GB 4824-2019 Industrial, scientific and medical equipment-Radio -frequency disturbance characteristics-Limits and methods of measurement>.

Note: Repeating any of the tests in GB 4793.1-2007 May damage the equipment and reduce protection against hazards!

1.9 EMC requirements statement

This product has been tested for The electromagnetic compatibility test, meets EN61326-2-6:2013 <Electrical equipment for measurement,control and laboratory use-EMC requirements- part 26: Particular requirements-In vitro diagnostic(IVD)medical equipment> and EN61326-1:2013 <<Industrial, scientific and medical equipment-Radio -frequency disturbance characteristics-Limits and methods of measurement - Part 1: General requirement>.Table 1 and Table 2 below for details.

It is the responsibility of the user to ensure the electromagnetic compatible environment of the equipment so that the equipment can work properly。

It is recommended to evaluate the electromagnetic environment before using the device。

This product is designed and tested according to GB 4824 Group 1 class B equipment suitable for use in all facilities, including household and residential public low voltage supply network directly connected to household

Do not use the device near a strong radiation source (such as an unshielded radio frequency source), otherwise it may interfere with the normal operation of the device。

Table I

electromagnetic emission	
launch test	compliance
GB 4824 Conducted Emission	Group 1 Class B
GB 4824 Radiated Emissions	
GB 17625.1 Harmonic emission	meet the requirements
GB/T 17625.2 Voltage fluctuation / flicker emission	meet the requirements

Table II

Electromagnetic Immunity

Immunity test	basic standard	Test value	Meet
Electrostatic Discharge (ESD)	GB/T 17626.2	Contact discharge: ± 2 kV , ± 4 kV Air discharge : ± 2kV , ± 4kV , ± 8kV	B
RF electromagnetic fields	GB/T 17626.3	3V/m, 80MHz～2.0GHz, 80%AM	A
burst	GB/T 17626.4	Power line ±1 kV (5/50ns, 5kHz)	B
surge	GB/T 17626.5	Line to ground: ±2kV Line to line: ±1kV	B
RF conduction	GB/T 17626.6	Power cord: 3V/m, 150kHz～80MHz, 80%AM	A
Power frequency magnetic field	GB/T 17626.8	3A/m , 50Hz	A
Voltage dips and interruptions	GB/T 17626.11	1 cycle 0%; 5 cycles 40%; 70% for 25 cycles; 250 cycles 5%	B B C C
Performance judgment: A. During the test, the performance is normal within the specification limit. B. During the test, the function or performance is temporarily reduced or lost, but can be recovered by itself. C. Temporary reduction or loss of function or performance during the test, but requiring operator intervention or system reset			

1.10 Technical parameters

Testing sample	Arterial or venous whole blood
Sample value	90-120 ul
QR code reading	Automatic QR code reading
Detection principle	Electrochemical detection technology for micro motors
Analysis method	Resistance method、current method and conductivity method
Temperature	37±0.3℃
Quality control calibration	The Analyzer automatically completes in real time
Working Environment	Temperature：5-32℃ Humidity：≤85%
Power supply	5V2A
Power rating	12VA
Operation interface	Linux system，4.3 inch800*480, IPS HD display, multiple language option
Storage	MAX 500,000 data
Printer	Built-in thermal printer

Data Interface	Type-C
Weight	1.2kg
Battery	3.7V 5000mAh

Chapter 2 Assembly

2.1 Unbox and check

Open the package according to the instructions of the packing box, carefully check the analyzer and the accessories according to the packing list, and then install the equipment according to the installation requirements and methods after confirming that there is no damage during transportation. If there are problems such as out-of- stock, wrong-stock, damaged parts, etc., please contact Seamaty or its authorized distributor in time. At the same time, please fill in the service guarantee form carefully , and return the product warranty card receipt to our company, so that we can track the quality of the product and carry out service in time. (or scanned and emailed back to our company: E- mail: **info@seamaty.com**).

Warning:

1、 Do not use if damaged after unpacking.

2、 Avoid dropping or bumping.

Caution :

Please save the packing material for future transportation or storage use.

2.2 Installation Requirements

2.2.1 Environmental requirements

- indoor use;
- Ambient temperature: 5 ℃～ 32 ℃;
- Relative humidity: ≤ 85 % ;
- Atmospheric pressure: 85.0kPa～106.0kPa.
- It is required to use the original power adapter for power supply, and the power socket used by the analyzer must be grounded.
- In order to ensure the normal operation of the instrument, the instrument should not be placed in the following places:
  a) Moisture, corrosive gas, dust, dander, strong electromagnetic field interference;
  b) crowded, unventilated places;
  c) Direct sunlight and other heat sources nearby;

d) Uneven and unstable countertops ;

e) The analyzer near a strong radiation source (such as an unshielded radio frequency source) , otherwise it may interfere with the normal operation of the equipment;

f) Place the water container or small metal next to the analyzer, so as to avoid water or metal objects falling into the instrument, causing a short circuit and damaging the instrument.

2.2.2 Power Requirements

- 5V2A, rated power: 12VA.
- It is not recommended to share a power outlet with high-power devices .

2.3 Switch the machine and install and print

2.3.1 Instrument switch

1. Take the instrument out of the carton and place it on a flat surface;
2. Check whether the appearance of the instrument is intact;
3. Press and hold the power button for 2s to turn on the instrument, the prompt light at the bottom of the screen lights up, the system starts, and the interface to be tested is entered.

[**Power on**] : Press and hold the power button for 2s and hear "di", release your finger, the instrument starts, the power indicator lights up, and displays startup loading interface as shown in Figure 2-1 .

Figure 2-1

After loading and initialization, the instrument displays the operation interface as shown in Figure 2-2.

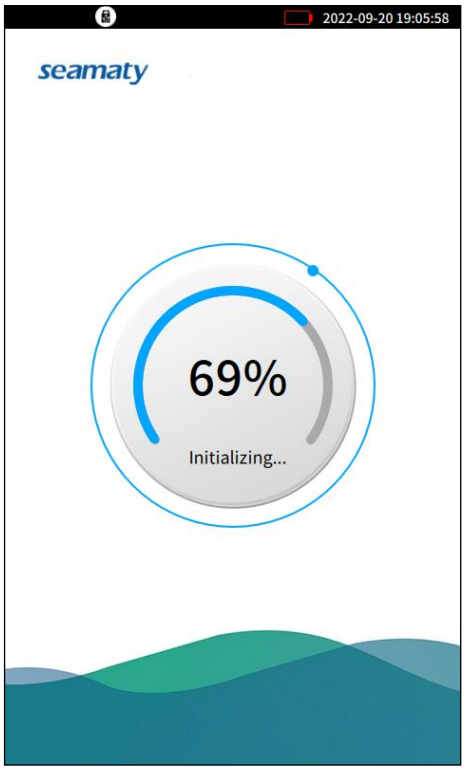


Figure 2-2

【 Shutdown 】 : Press and hold the power button for 2S, the instrument will be powered off and shut down (during the test, do not shut down.)

Tip: In order to prolong the service life of the instrument and accessories , it must be operated in accordance with the prescribed shutdown procedures , and do not switch on and off frequently.

Please keep the dismantled accessories properly .

2.3.2 Installing the printing paper

The printing paper used by this instrument is 57*40mm thermal printing paper, the internal structure is shown in Figure 2-3

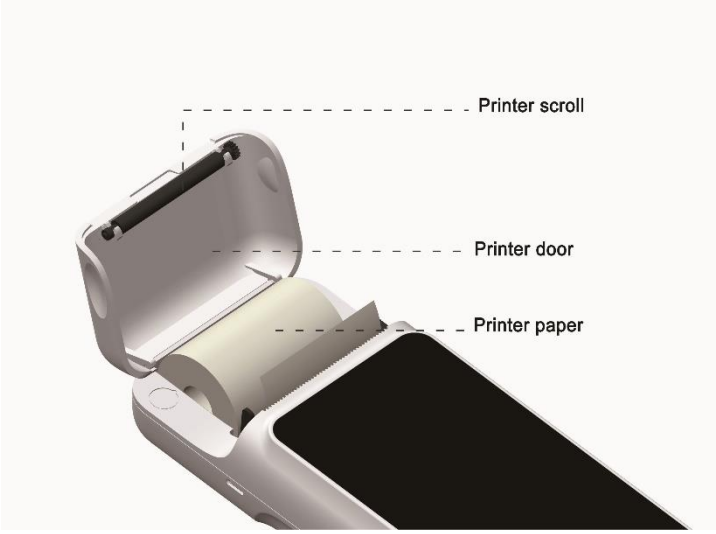


Figure 2- 3

The installation steps are as follows:

1) Open the printer door;

2) Remove the packaging of the printing paper and put it into the groove, as shown in Figure 2-3. **Pay attention to the front and back of the thermal paper**.

3) Hold the end of the printing paper, go around the shaft and make the printing paper stick out from the paper outlet of the printer door;

4) Close the printer door and lock the latch to complete the installation.

Note: The printing paper has been installed when the instrument leaves the factory. If the user runs out of printing paper and installs it by himself, follow this method.

2.2.3 Installing an external printer

This device supports printers with the **HP PCL3GUI** printer language as standard, such as the HP Jet lnk Advantage Ultra 2529.

If you do not need to use an external printer to print the test report, please skip this section.

The installation steps are as follows:

1) Install and set up the printer according to the printer's instruction manual;

2) Place **A4** size printing paper;

3) Use the **Type-c** to **USB** adapter cable to connect the **OTG** data interface of the instrument and the USB connection cable of the external printer ;

4) Turn on the power of the printer and it is ready to use.

Chapter 3 Introduction to Common Operations

3.1 Power-on inspection and commonly used buttons

After the instrument is turned on, it will automatically enter the interface shown in Figure 3-1. The user must firstly ensure that the date and time displayed in the upper on right corner of the screen are correct, otherwise, the date and time must be reset by referring to 3.1.1 of this chapter.

There are four main keys on the operation interface, as shown in Figure 3-1. The functions of each key are explained as follows.

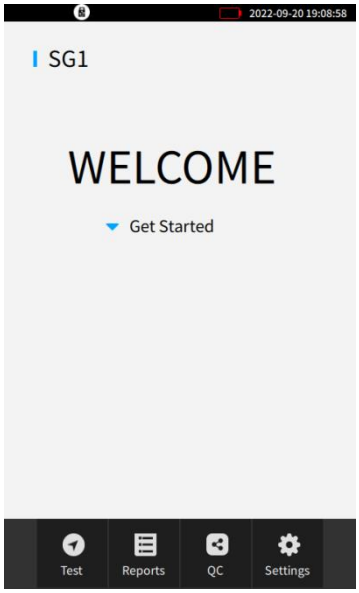


Figure 3-1

3.1.1 System Settings

This button is used to set system date, time, hospital name, printer mode, sample/control reference value, etc. Click 【System Settings】 on the main menu interface, and set it in the pop-up dialog box, as shown in Figure 3-2.

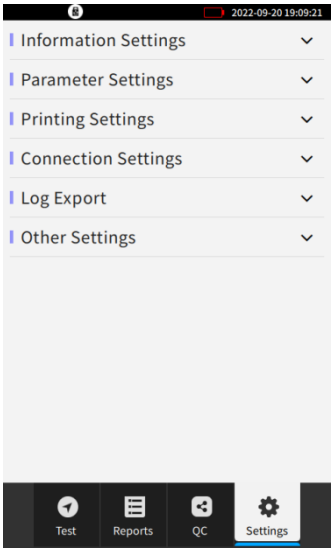


Figure 3-2

Click the corresponding setting module, the corresponding module will be expanded, click again, the module will be collapsed

3.1.1.1 Instrument Information Setting

Click 【Instrument Information Settings】 to enter the instrument information setting interface, where the user can set the instrument time and hospital name, as well as view the instrument model and instrument ID, as shown in Figure 3-3.

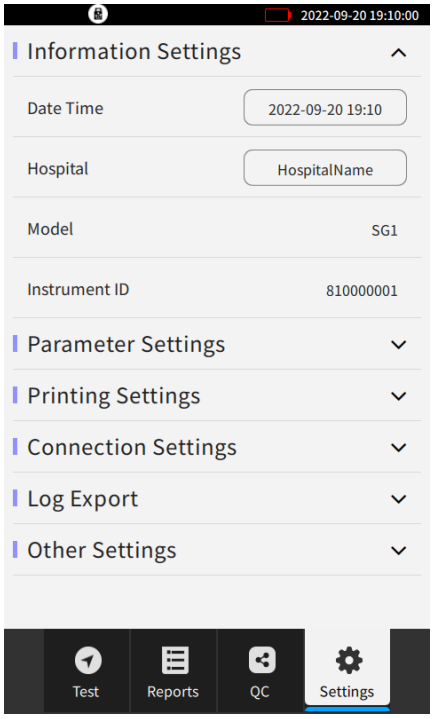


Figure 3 – 3

Figure 3-4

【Set date and time】The system date and time are set according to Beijing time before leaving the factory. Click the "system time" column to enter the interface as shown in the figure.

In the interface shown in 3-4, scroll to select the desired date and time and click OK to take effect

【Hospital name】 Users can customize the hospital name according to the actual situation.

3.1.1.2 Parameter setting

Click 【Parameter Setting】 to enter the parameter setting interface, as shown in Figure 3-5

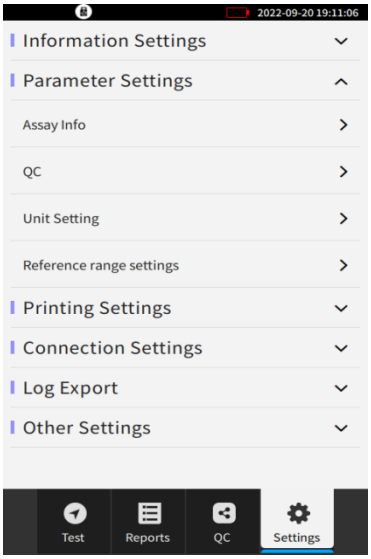


Figure 3-5

Project Information

Click 【Project Information】 to enter the interface as shown in Figure 3-6

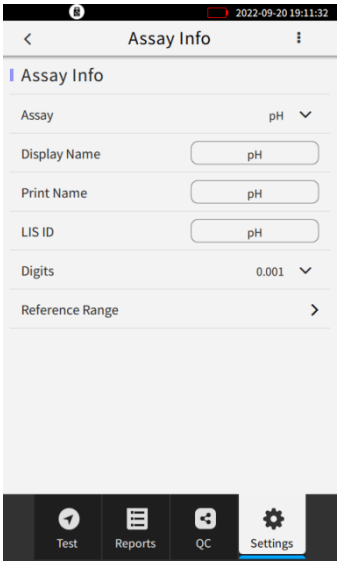


Figure 3-6

Users can view and set the name, unit, precision, difference reference and other information of each item.

【Difference Reference】 setting: Click Diff Ref" in the interface as shown in Figure 3-7 to enter the interface as shown in Figure 3-7

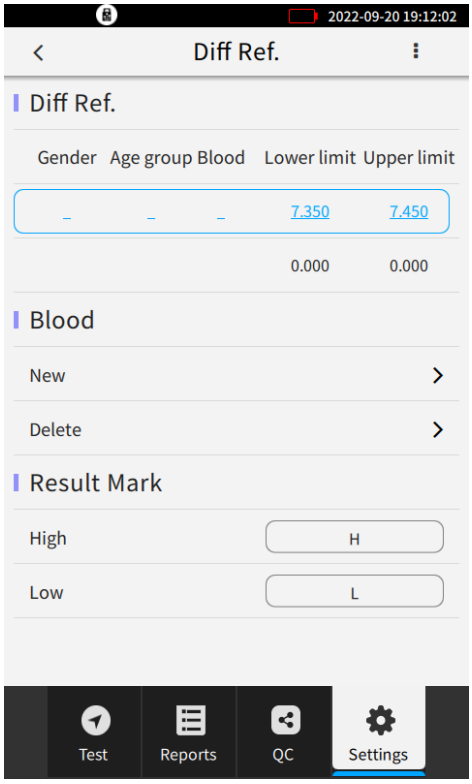


Figure 3-7

- Users can view and edit the reference range related information of the corresponding conditions of the project;

- The user can add and delete sample types at the bottom of the interface in Figure 3-7; modify the result mark.

Quality Control Settings

Click 【QC Settings】 to enter the quality control settings interface as shown in Figure 3-8

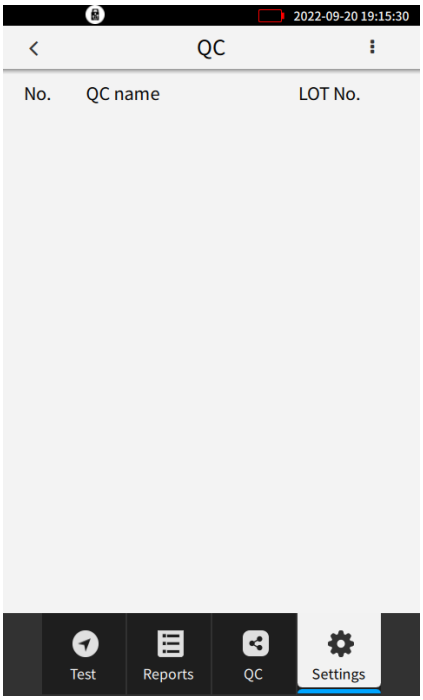
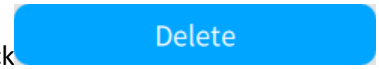


Figure 3-8

Click on the top right corner  and click 

Enter the 【**quality control setting** interface as shown in Figure 3-9; click 

, The currently selected QC information can be deleted.

The user can enter【target value】, 【lower limit】 and [upper limit] after the corresponding item to set the quality control information for it;After setting， click  ,the settings can be saved.

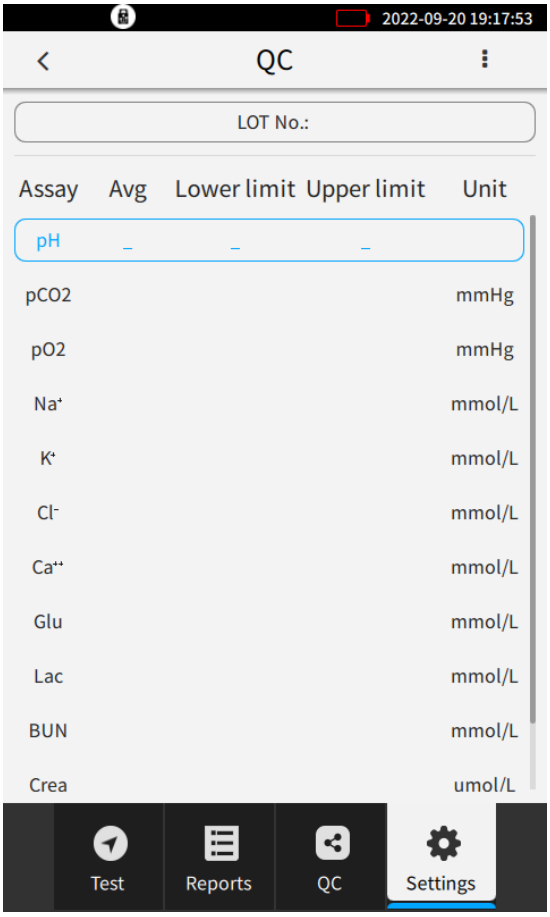


Figure 3-9

Unit setting

Click 【Unit Settings】to enter the interface as shown in Figure 3-10, The user can view the unit used by all projects and set the unit of the project on this interface.

After setting， click ⋮ ,The settings can be saved.

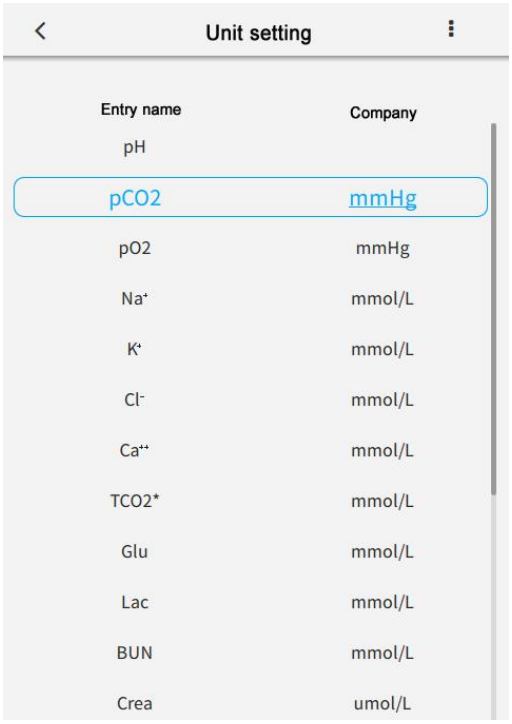


Figure 3-10

Reference range setting

Click 【Reference Range Setting】 to enter the interface shown in Figure 3-11

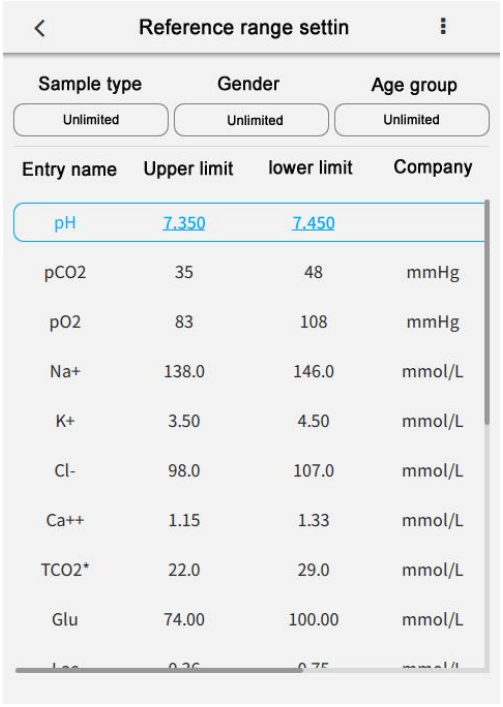


Figure 3-11

The user can view the reference range of all projects and set the reference range of the project on this interface.

Click the content of the corresponding item to edit the settings; After setting，click ⋮,The settings can be saved.

3.1.1.3Print Settings

Click the 【Print Settings】 title on the 【System Settings】 interface to expand the interface as shown in Figure 3-12

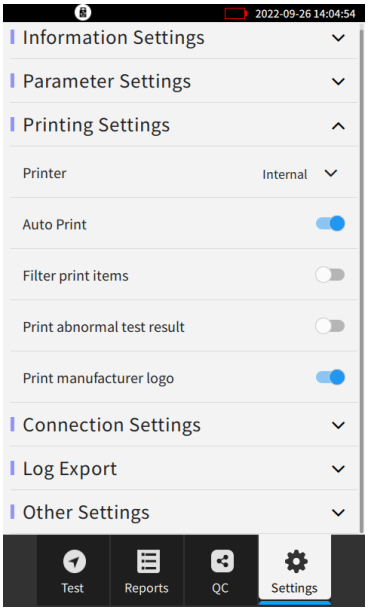


Figure 3-12

【Printer】Choose the built-in/external printer

【Auto Printing After Testing】 Select whether to automatically print the test report after testing or not.

【Print Abnormal Test Results】If there are test exceptions in this test sample, you can select whether to display the exceptions in the test report or not.

【Print the Manufacturer's Logo】 Select whether to print the manufacturer's logo in the test report.

3.1.1.4【Connection Settings】

Click the 【Connection Settings】 title on the 【System Settings】 interface to expand the interface shown in Figure 3-13.

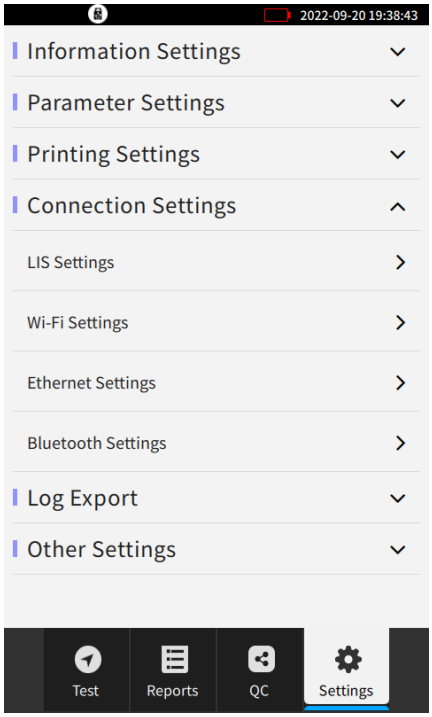


Figure3-13

【Lis setting】

Relevant settings for connecting the LIS system, including 【Start LIS】 button， connection method, serial port settings, and network settings as shown in figure3-14

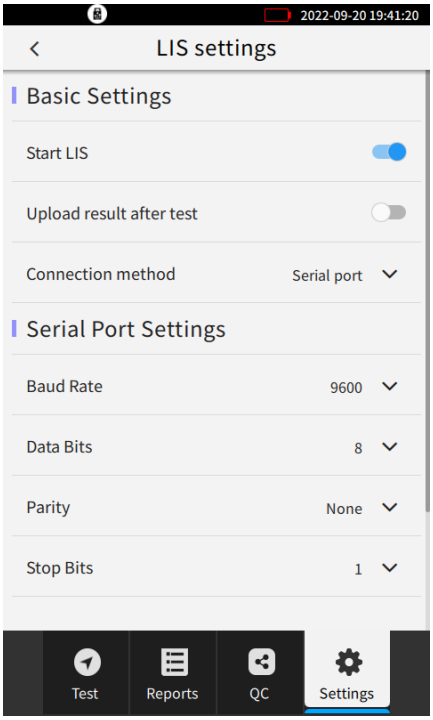


Figure3-14

【Connection method】 : support using serial connection and network connection;

Parameters about 【Serial Port Settings】 will be automatically showed after users chooses the 【Connection Method】 of ‘‘Serial Port’’.

After you set the serial port parameters as the same parameters of your server, LIS transfer will be conducted at the page of 【Sample Data】.

【Network connection】

Parameters about 【Network】 setting will be automatically showed after users choose the 【Connection Method】 of ‘‘Network’’, as shown in Figure 3-15

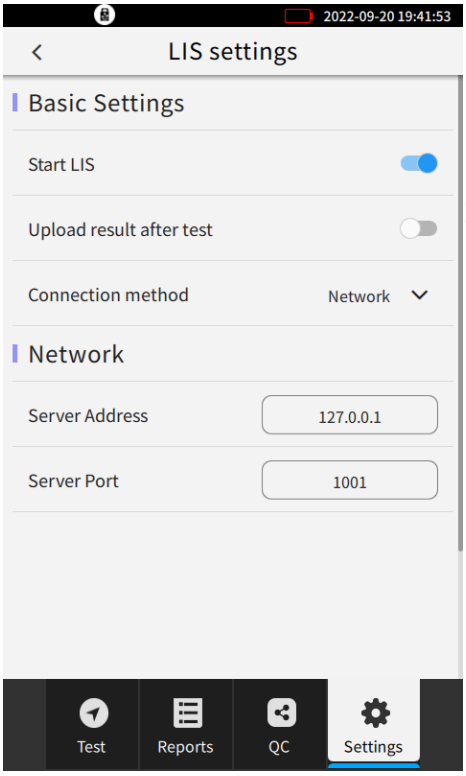


Figure 3-15

The server of equipment and LIS should be in 【the same network】 for LIS transfer when using the connection method of 【Network】’.

After users set 【Server Address】 and 【Server Port】 , LIS transfer will be conducted at the page of 【Sample Data】.

Connection Protocol: Data transfer uses HL7 standard transfer protocol, version v2.1.3;

Note: When turning off the【Start LIS】 button, the page of [Sample Information] will hide relevant 【Lis Upload】buttons.

【 Wi-Fi Settings】

WiFi function settings. Users can upload data to the LIS system and upgrade the system online by network transfer after connecting with WiFi.

【Ethernet setting】 Turn on/off the button. There are two connection types, namely Dynamic IP and Static IP, as shown in figure 3-16

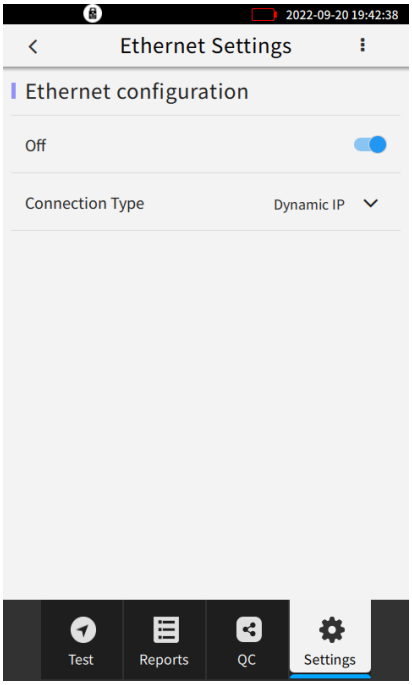


Figure: 3-16

【**Bluetooth Settings**】 Bluetooth settings , switches and Bluetooth connection. As shown in the figure: 3-17

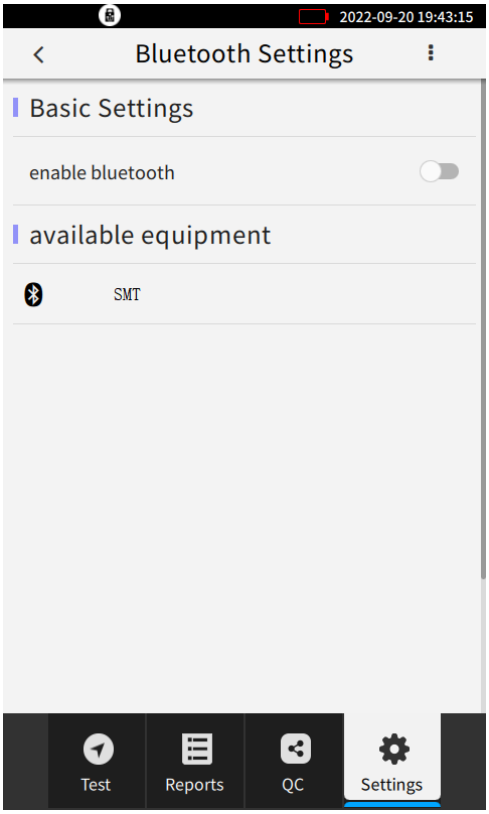


Figure 3-17

3.1.1.5 【Log Export】

【Log Export】 Export instrument log and data files;

Instrument Log: Record instrument effort files;

Data Files: Record data files that have been tested by the instrument. Database files can back up test data, which can be imported into the instrument via the data import function.

Note: This function requires the insertion of a U-disc.

3.1.1.6 **Other Settings**

Click the button of 【Other Settings】 at the page of 【Settings】, as shown in 3-18.

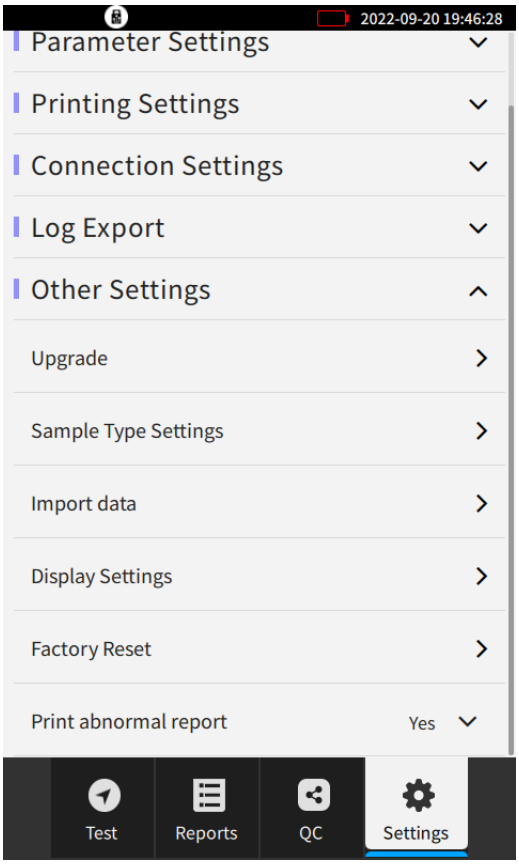


Figure 3-18

【Upgrade】

Click the button of 【Upgrade】 then enter the page as shown in figure 3-19.

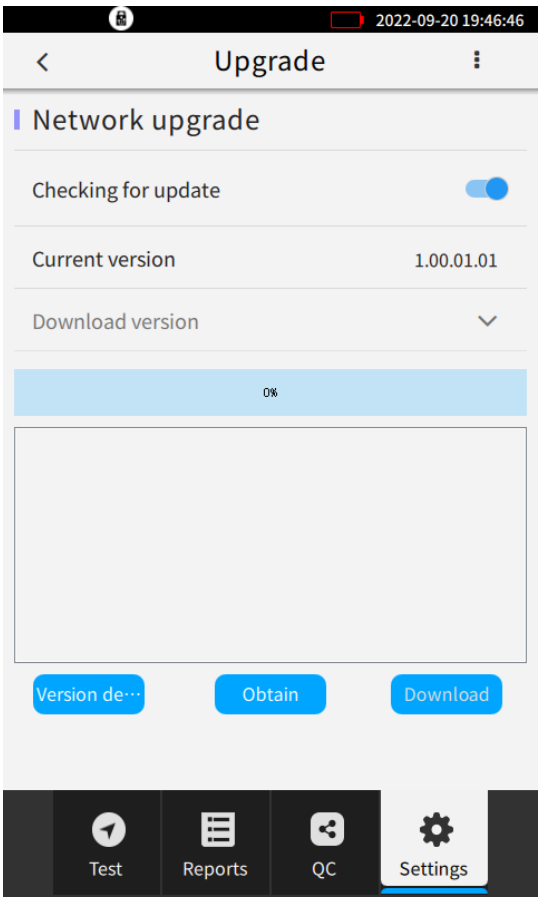


Figure 3-19

【Sample Type Settings】

Set sample type information such as add new sample, delete sample, and whether to use this type of sample or not, as shown in figure 3-20.

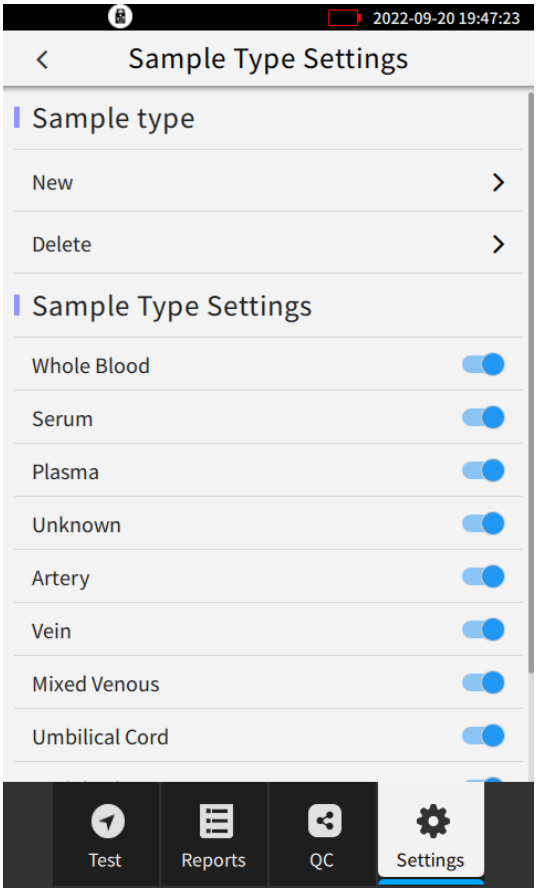


Figure 3-20

Sample Type:

Click【New】, type the new sample name and click 【OK】 to save this sample type;

Click 【Delete】, type the sample name that you want to delete and click 【OK】 to remove this sample type.

Sample Type Settings:

After turn off the relevant button of a sample type, it won't be shown anymore when you fill out the sample information.

【data import】

This function can import the 【database】 files exported in section 3.1.1.5 into the equipment, allowing the data within the database to be overridden into the current equipment.

The page is shown in figure 3-21:

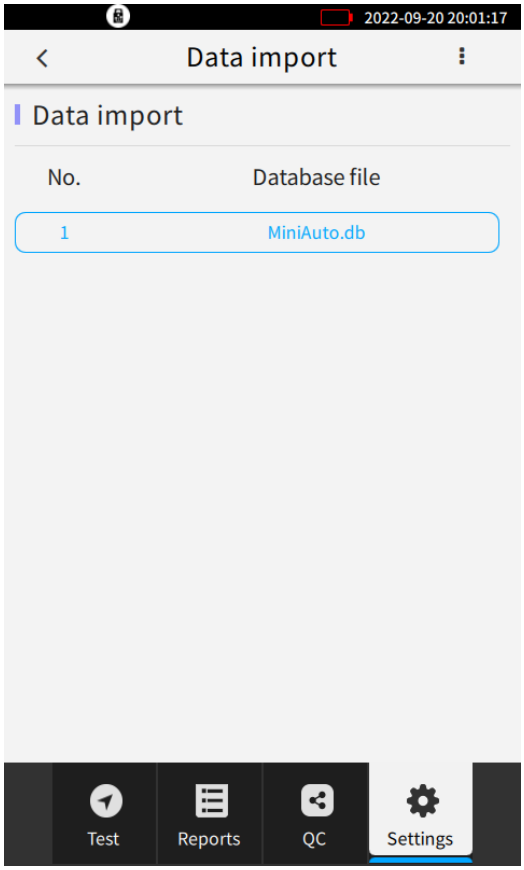
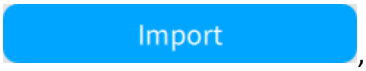


Figure 3-21

Click on top right button  , then click 

, the operation will be finished after confirmed import.

【display setting】

To set relevant parameters about display settings, as shown in figure 3-22

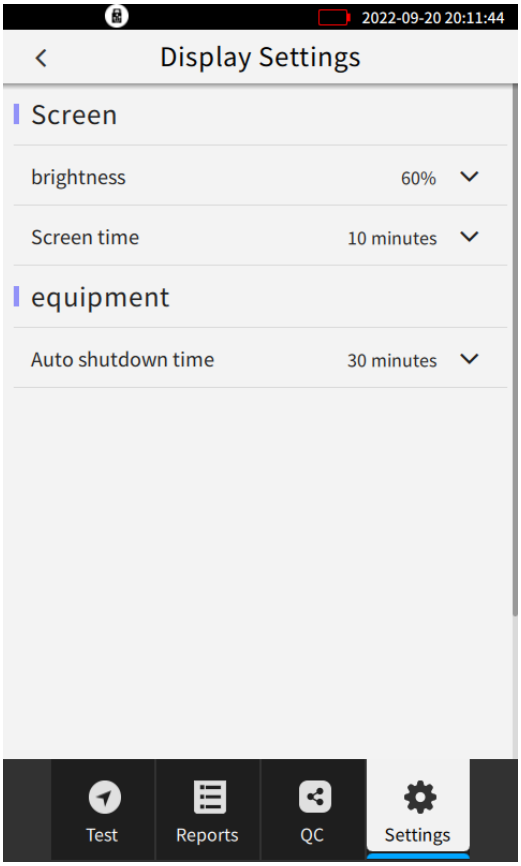


Figure 3-22

[Screen]

【Brightness】Set the screen luminance by selecting relevant percentage.

【Screen time】 Set the analyzer rest screen time. The automatic rest screen will be held and the screen awakens by clicking when standby time longer than this interval.

【Equipment]

Auto shutdown time】 Set the analyzer auto shut down time. It'll automatically shuts down when the standby time exceeds this interval.

【Restore factory settings】

【Factory Reset】

This function will clear all test data and settings for the equipment. A prompt box pops up upon clicking. Click 【OK】 to confirm your operation or click 【cancel】 to cancel your operation, as shown in figure 3-23.

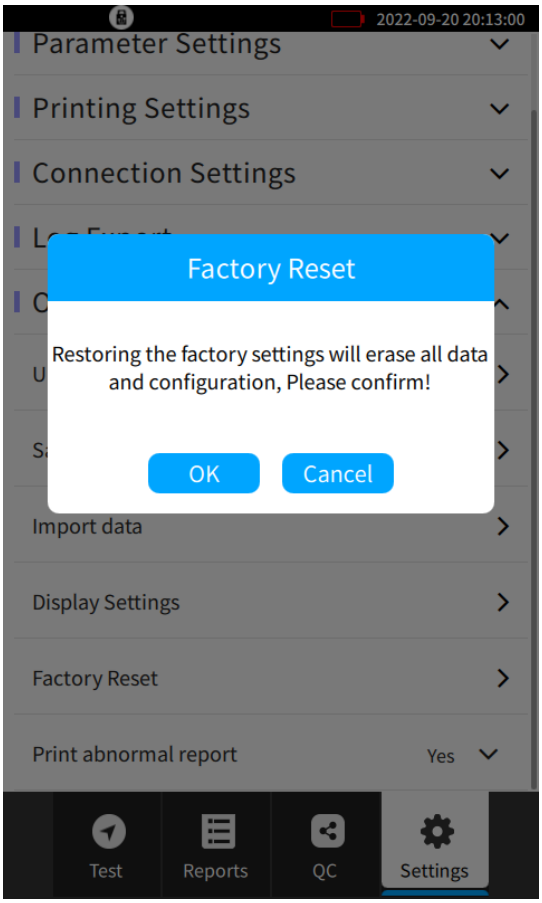


Figure 3-23

Note: This operation will delete all test data in the instrument, please operate with caution.

【Print Exception Report】

Whether to save the test result when setting the test exception.

Note: When this configuration is turned off, the test will not be saved after an error is reported during the test process, please use it with caution.

3.1.2 Sample data

This button is used to query historical sample information and test results, and can realize the functions of querying, modifying sample settings and printing sample information. The interface is shown in 3-24

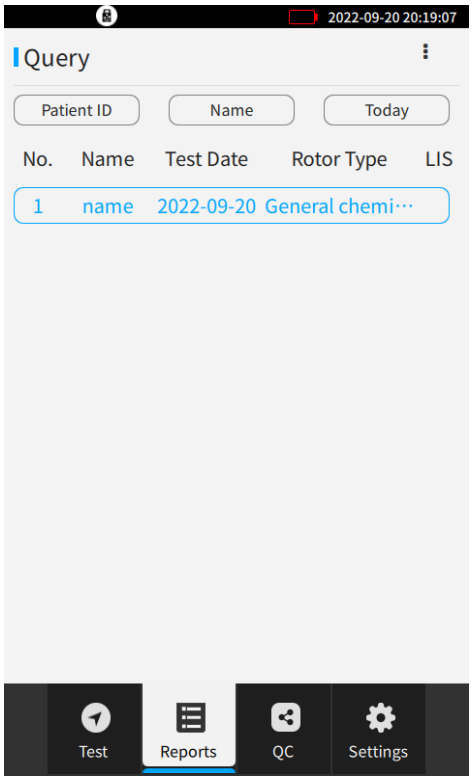


Figure 3-24

【**Query function**】There are three query conditions, name, test date and medical record number; after selecting or entering the required conditions, the interface will automatically display the query content.

【**Data processing**】 Click【⋮】to enter the interface shown in Figure 3-25

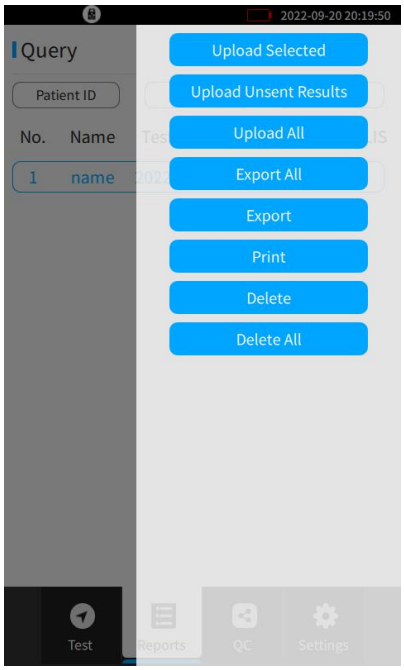


Figure 3-25

Click 【Upload】, the user can upload the selected test record to the LIS system (the connection to the LIS system needs to be successful);

Click 【Export】, the user can export the test report of the selected test record;

Click 【Print】 to print the test report of the selected test record;

To modify/view sample information:

Click the corresponding test record to enter the interface as shown in Figure 3-26 to view and edit sample information and view the test data and reference range of the current test record.

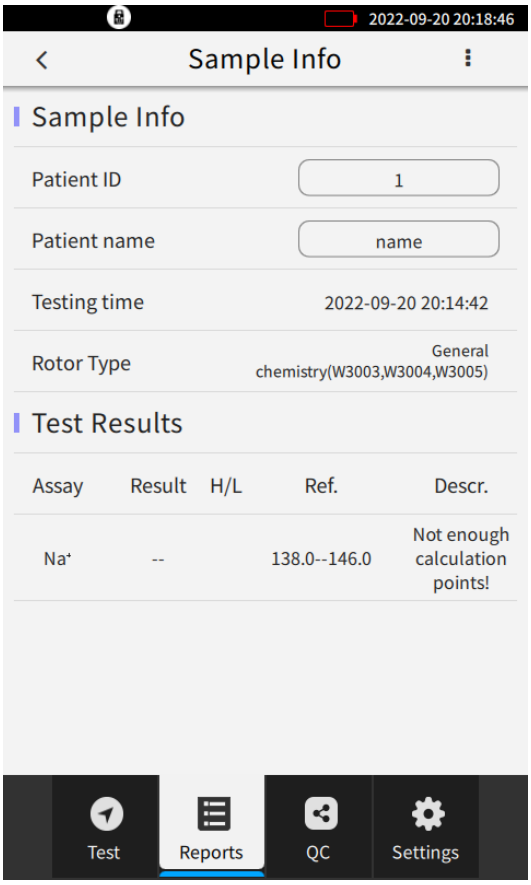


Figure 3-26

Note : When clicking the 【Sample Information】 area, the interface will expand to display all the sample information contents

3.1.3 Quality Control Data

This button is used to query historical quality control information and test results, and can realize the functions of querying, modifying quality control information and printing test records. Click this button to pop up the interface shown in 3-27

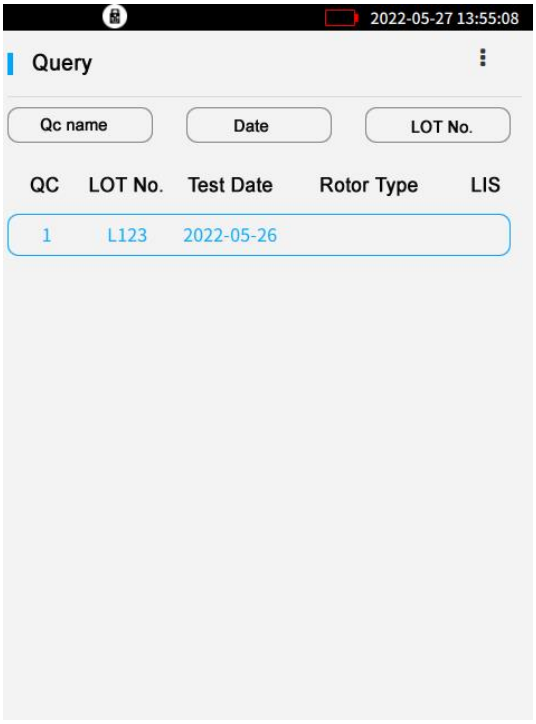


Figure 3-27

For the operation process of this interface, please refer to chapter 4.1.2 【**Sample Information**】module description.

3.1.4 Preparing for Test

sample or quality control product to the reagent card, insert it into the reagent card slot of the instrument, and click the 【 Prepare Test】button to enter the pre-test process.

If there is a prompt , please observe the prompt and operate it. For details of the test process, see 4.3 【Sample Test】

3.2 Operating the soft keyboard

3.2.1 Soft Keyboard Window

The instrument has a built-in soft keyboard, the user can click the position to be input in the window, the cursor flashes, and the soft keyboard is activated. This operation can control the soft keyboard to switch between three states: closed, English input, and Chinese input. Click the editable dialog box to pop up the soft keyboard dialog box, as shown in Figure 3-28.

Figure 3-28

3.2.2 Keyboard input method

English input method :

Click "  " , switch to English input HospitalName , click  or the blank to exit. As shown in the figure: 3-29

Figure 3 - 29

【Chinese input method 】 The default state is generally Chinese input mode. When entering English input method, click "  " to switch Chinese input mode. As shown in the figure: 3-30

Figure: 3-30

Chapter 4 Tests and Results

4.1 Sample Requirements

Warning :

Please follow the instructions for use with the reagent card!

4.2 Preparing the reagent card

4.2.1 Reagent Card Storage and Handling

For details, please refer to the instructions of the supporting Prite reagent card.

4.2.2 Add sample

1. Transfer the sample to the reagent card with a disposable gun head, not less than the sample size corresponding to the number of detection items
2. In order to avoid cross-contamination, the same tip cannot be reused to absorb multiple samples.

Remark：

1. Do not contaminate or damage the two-dimensional bar code of the reagent card;
2. Do not touch the tip of the pipette tip to avoid affecting the test accuracy of some items;
3. After the sample is completed, the disposable gun head is placed in the biological garbage bin.

4.3 sample test

1） start-up preparation;
2） Enter into the self-test and warm-up process ;

Note: The main interface of the software is entered normally when the machine is turned on . In order to ensure the stability of the temperature of the test chamber of the instrument , the official test can be entered after preheating for 3 minutes .

3） Click [Prepare Test] to enter the interface shown in Figure 4-1;

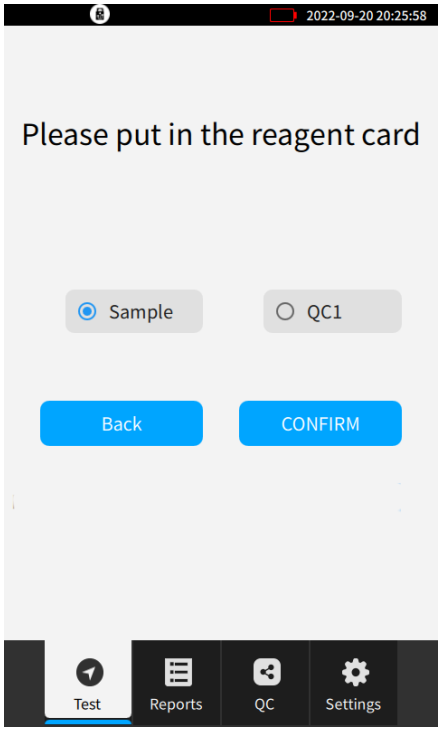


Figure 4-1

4） Place the reagent card that has been added to the sample in the reagent card slot, and click [Start Test] to enter the interface shown in Figure 4-2

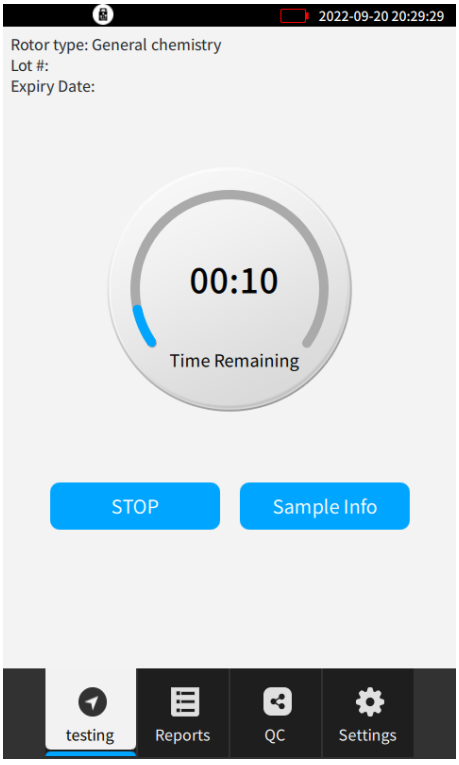


Figure 4-2

5） After the test starts, you can click [Sample Information] to fill in the sample information and click “ ┇ ” [Save]; the interface shown in Figure: 4-3;

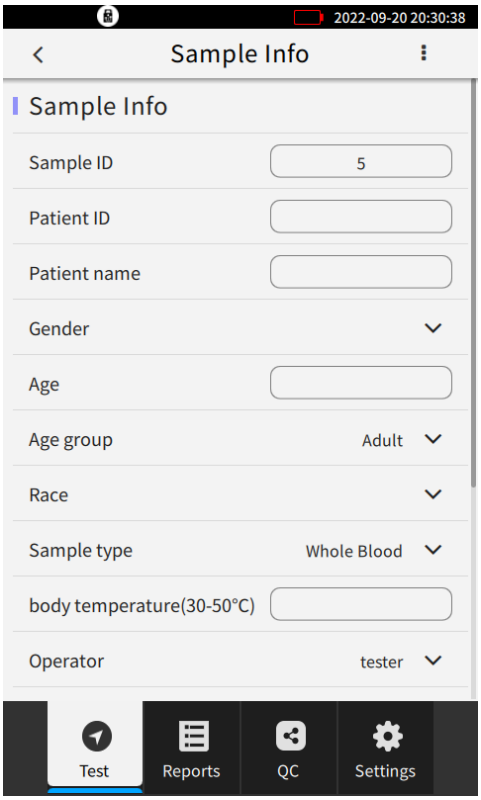


Figure 4-3

6） When the remaining time displayed in the test interface is exhausted, the test is completed, and the test results can be viewed in the sample data/quality control data.

4.4 Test program considerations

Instrument

- Check that the ambient temperature of the machine is at 5–32 ºC
- Do not abruptly shut down and disconnect the power during operation
- Before starting the test, insert the reagent card
- Do not disassemble the machine at will, human damage is borne by the user himself

Reagent card

- Do not print on the packaging label with an expired reagent card and shelf life
- After the reagent card is opened, please use it within one month

4.5 Calibration and quality control testing

4.5.1 Calibration

Blood gas& electrolyte analyzers undergo standard calibration procedures before leaving the factory. The analyzer performs a self-test procedure after power-on, and if the self-test fails, it prompts a warning message. All items included in each reagent card have been calibrated at the factory before shipment, the calibration information is included in the QR code on the reagent card label, and the analyzer's built-in intelligent quality control system (RQC) monitors internally each time the test is performed to ensure the reliability of the output results..

4.5.2 Quality Control

The performance of a Blood gas & electrolyte analyzer or reagent card can be verified by quality control assays. Specimens prepared for quality control are called quality controls, and the reference material of the quality control is the same as that of the test sample.

The company recommends that customers do quality control at least once a month, recommend the use of RANDOX or Bio-red quality control, and when the laboratory conditions of the analyzer change or the test results do not match the patient's clinical performance, they should also do quality control to verify, or comply with the local national and regional regulations and hospital regulations.

Enter the [Prepare for Test] interface, put in the quality control and install it. Please refer to 5.2.2 Sample the operation process of adding quality controls.

The test process is shown in Section 5.3 as shown in Figure 4-4.

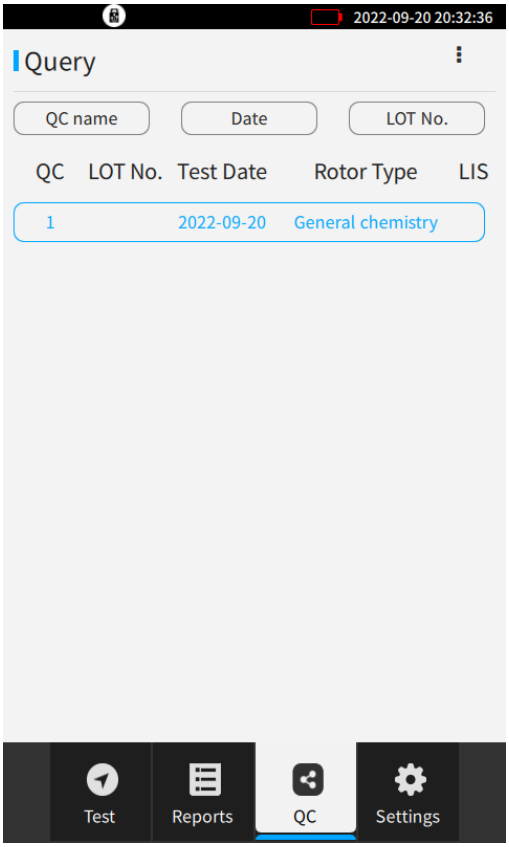


Figure 4-4

Note: The QC test cannot add the required test items by "directly clicking on the project", and can only add the test project by "selecting the project combination" of the same test

Click Start Test to start testing.

The user clicks on the corresponding test displayed to edit the [Quality Control Information]

4.6 Print the results

4.6.1 Built-in printer prints reports

4.6.1.1 Sample reports

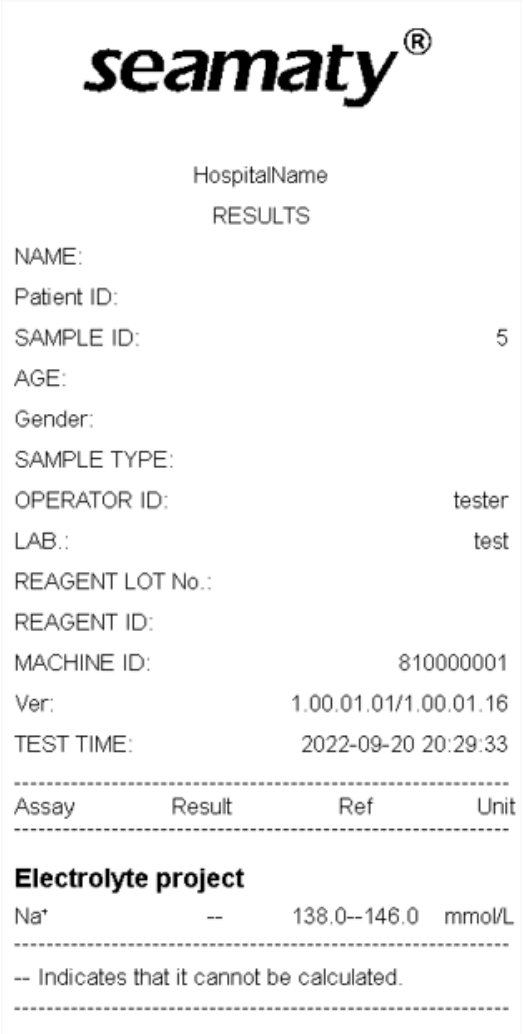
The results of the machine test are automatically stored and the user can choose to print or find them.

The following figure shows a general sample test report. This is shown in Figure 4-5.

1） The letterhead information of the printed report includes: hospital name, name, medical record number, sample number, age, gender, sample type, examiner, department, reagent batch number, reagent card ID, instrument ID, version, test time.

2） The printed result section has four columns, item name, analysis concentration, reference range, unit.

The deviation of the detected value from the reference value will be marked with "H" (high) and "L" (low) next to the concentration.


seamaty®

HospitalName

RESULTS

NAME:

Patient ID:

SAMPLE ID: 5

AGE:

Gender:

SAMPLE TYPE:

OPERATOR ID: tester

LAB.: test

REAGENT LOT No.:

REAGENT ID:

MACHINE ID: 810000001

Ver: 1.00.01.01/1.00.01.16

TEST TIME: 2022-09-20 20:29:33

Assay	Result	Ref	Unit
Electrolyte project			
Na^+	--	138.0--146.0	mmol/L

-- Indicates that it cannot be calculated.

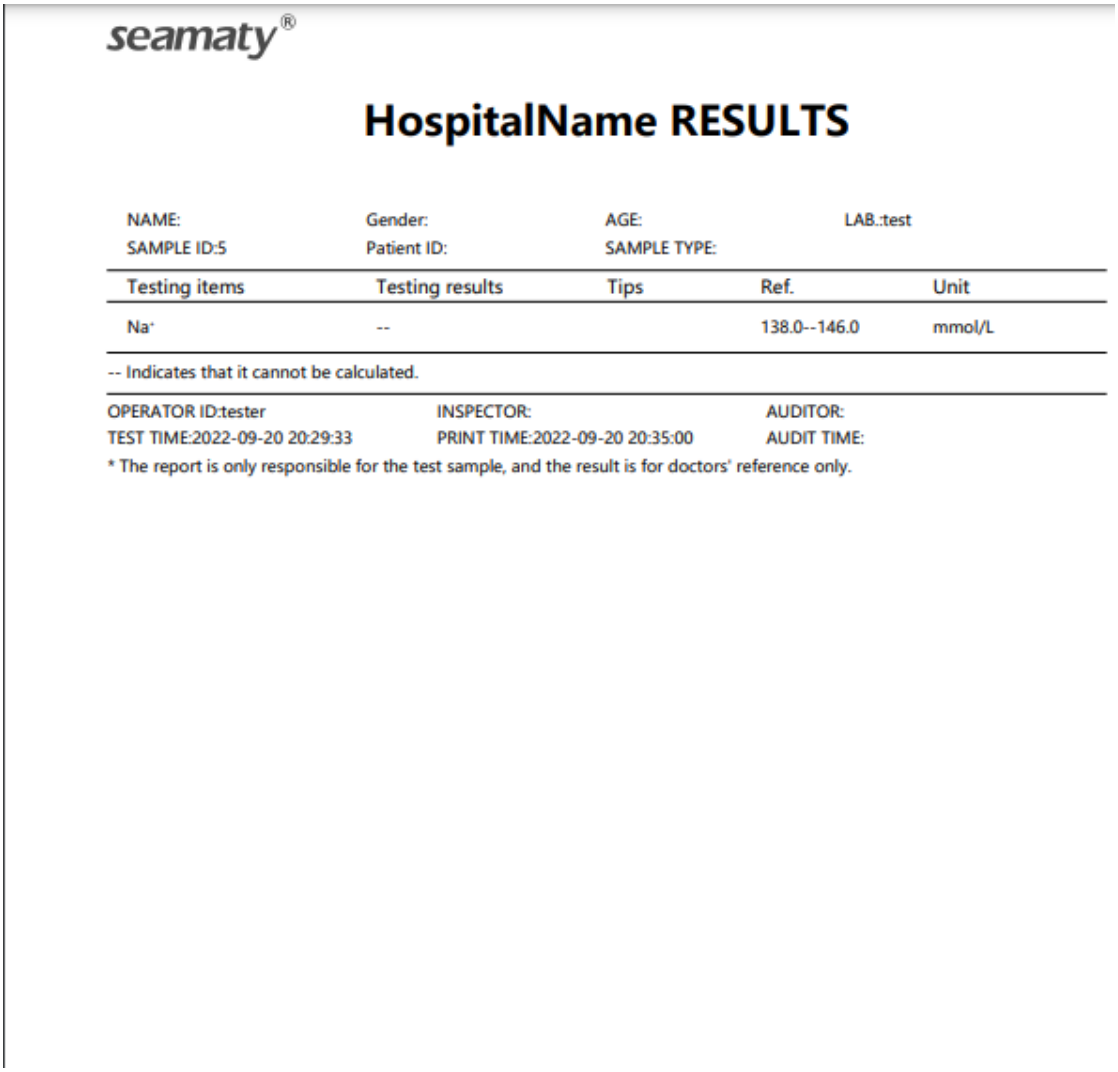
Figure 4-5

4.6.2 An external printer prints the report

4.6.2.1 Sample reports

The sample print report is shown in Figure 4-6.

It is recommended that users use HP external printers, such as HP DeskJet lnk Advantage Ultra 2529。



seamaty®

HospitalName RESULTS

NAME:	Gender:	AGE:	LAB.:test
SAMPLE ID:5	Patient ID:	SAMPLE TYPE:	

Testing items	Testing results	Tips	Ref.	Unit
Na^+	--		138.0--146.0	mmol/L

-- Indicates that it cannot be calculated.

OPERATOR ID:tester	INSPECTOR:	AUDITOR:
TEST TIME:2022-09-20 20:29:33	PRINT TIME:2022-09-20 20:35:00	AUDIT TIME:

* The report is only responsible for the test sample, and the result is for doctors' reference only.

Figure 4-6

Chapter 5 Maintenance and Service

SG1 requires a minimum of care and maintenance. Clean and maintain it periodically to ensure its optimum performance.

5.1 Cleaning

5.1.1 Cleaning the exterior surfaces

Clean the exterior of the machine once a week with a mild detergent and a soft damp wool rag.

Do not spray or pour any detergent or liquid directly on the machine. Use a moistened soft rag or disposable paper towel to wipe the machine.

Attention：

a) If hazardous substances leak on the surface or onto the internal of the machine, then proper disinfection should be taken by wiping with alcohol containing 75%.

b) Do not use detergents and disinfectants that might have chemically react with machine parts or materials contained in the machine will cause a danger.

c) If there is any doubt about the compatibility of the detergents and disinfectants with the machine components or materials contained within the equipment, please contact the manufacturer or the agent.

5.1.2 Cleaning the display

Periodically wipe the display with a moistened lint-free towel.

5.2 Software Upgrade

The software needs an upgrade when the following two conditions are encountered.

A. the manufacturer has a unified release of upgrade notice for this software.

B. The software of the analyzer is requested to be upgraded by the after-sales personnel during the after-sales maintenance.

This product supports U disk or network upgrade.

Note: There are risks in upgrading, please read the upgrade steps or tips carefully before upgrading, and check carefully to confirm whether the software upgrade package and software version are correct to avoid damage to the instrument caused by upgrade errors.

5.2.1 USB flash drive upgrade

1）Prepare a USB flash drive with the file system in FAT32 format. If the format is incorrect or cannot be confirmed, please format it on your computer and back up the data on the USB drive by yourself before formatting.

U disk formatting steps：

1) Insert the USB drive into your computer ---- click to select the USB drive ---- right mouse click ---- format ---- file system select "FAT32" ---- start ---- confirm ---- pop up formatting complete prompt ---- confirm.
2) Obtain the software zip package from the company's website or after-sales service personnel, see Chapter 7 for details of the company's website and after-sales service hotline.
3) Create directory SMT810 in the root directory of the U disk, place the downloaded or obtained software zip file under the SMT810 file in the root directory of the U disk, the U disk is ready.
4) Unplug the USB flash drive from the computer and connect it to the OTG data transfer interface of the instrument via an adapter cable.
5) Power on the analyzer and enter the system settings - other - version upgrade - " ┇ " - select the U disk upgrade and then shut down and reboot.
6) The analyzer starts, the software prompts the version upgrade information, confirm that the upgrade version number is the same as the version number of the software zip package, select [Yes], the software starts to upgrade.
7) The software upgrade process will prompt the user upgrade completed, after completion the instrument needs to restart, the user should shut down and restart the machine.
8) After the software upgrade is completed, it will be initialized automatically and the upgrade is completed.

Note: When upgrading, if the upgrade fails or other abnormalities occur, please restart the analyzer, and if it is still unsuccessful after restarting, please contact the company's after-sales service personnel, see Chapter 7 for details of the after-sales service hotline.

5.2.2 Network Upgrade

The instrument software can be upgraded by connecting to the network, this function requires a WiFi or Ethernet connection to the network

Operating Instructions:

After connecting to the network via WiFi or Ethernet, click [Version Upgrade] under [Other] in the [System Settings] screen.

Enter the interface as shown in Figure 5-1

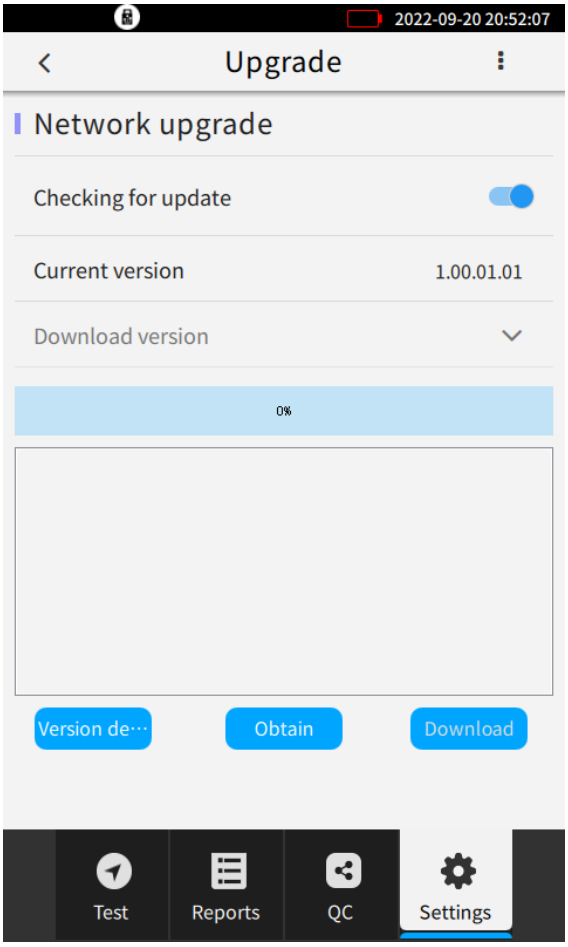


Figure 5-1

Click [Upgrade] to get the downloadable software version, click the drop-down menu to select the required software version and then click [Download] to start downloading, the download progress is shown in the progress bar, after the download is complete, reboot to start the upgrade, the upgrade process is as in section 5.2.1.

If the display for the U disk upgrade, please switch to network upgrade in the " ┇ ".

5.3 Simple Troubleshooting

Fault	Solution
The instrument cannot turn on normally	Check if the instrument is powered on Check the access voltage
Cannot access the test screen	Restart the instrument
Touch screen does not work properly	Not operating in charging
Mouse cannot be moved	Reconnect the mouse Connect the mouse to your computer and make sure it is not damaged Reboot your computer
Built-in thermal printer cannot print	Check if the built-in printer is selected in the system settings Check if the thermal paper is installed correctly

External printer cannot print	Check whether the external printer is selected in the system settings Check whether the printer USB cable is reliably connected Verify that the printer model meets the requirements of the machine
Soft keyboard does not work	Use this button in other screens Reboot
QR code cannot be recognized	heck if the QR code has been contaminated or damaged
The instrument cannot be turned on	Check whether the power is insufficient to automatically shut down, check the battery aging, damage or poor battery power supply, power IC is not normal

Note: If none of the above can be solved, please contact the after-sales service.

5.4 Consumables Replacement

Name	**Material Properties**	**Description**
Print paper	Consumables	Users replace the standard specifications of the instrument, the printer paper used in this instrument is 40*57mm thermal printer paper

Attention：

1. The internal devices need to be replaced by our designated or authorized professionals.
2. Users should clean or maintain the test chamber regularly according to the usage.

Chapter 6 Packaging, Storage and Transportation

6.1 The instrument is packaged in a rigid carton outside and high-quality pearl cotton foam inside, which is firm and shockproof.

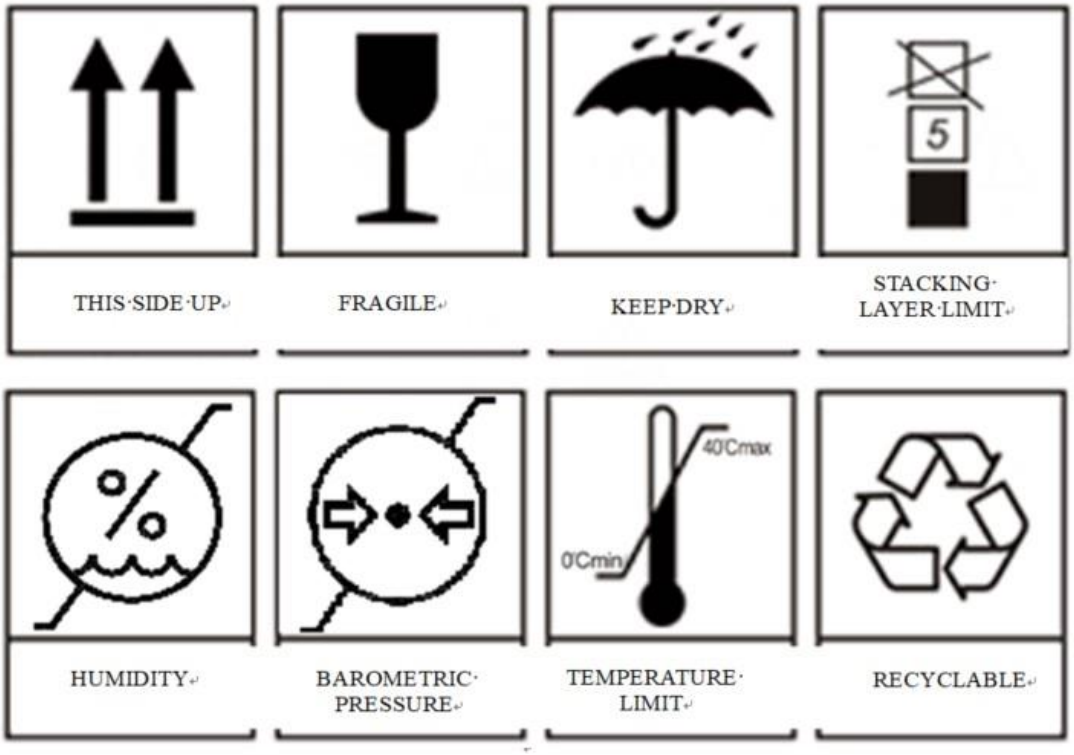
6.2 The instrument packing box is equipped with simple anti-shock facilities, which are suitable for air, railway, road and ship transportation, but should avoid rain and snow splashing, inversion and collision.

6.3 When the storage period of the instrument exceeds 3 months, the instrument should be taken out of the packaging box, powered on for 4 hours, and after checking the running status, put the instrument in the box according to the direction shown on the packaging box and place it in the warehouse.

6.4 Do not stack the instruments, and do not close to the ground, walls and roofs.

6.5 Ambient temperature for transportation: -20 ℃～+ 55 ℃; Ambient temperature for storage : 0 ℃～+40℃; Relative humidity: ≤85 %.

6.5.1 Outer box identification



Chapter 7 Company Contact Information

Production information

Chengdu Seamaty Technology Co.,Ltd

Room 306-316 of No.1 Floor 1 Building1 and Floor 4 South Part of No.1 Floor 1 Building 2, No.333 Hezuo Road, Hi-Tech Zone 611731 Chengdu, Sichuan Province, P.R.China

MedNet EC-REP GmbH

Borkstrasse 10, 48163 Münster, Germany

After-sales service

After-sales service provider: Chengdu Seamaty Technology Co.,Ltd

After-sales service address: Room 306-316 of No.1 Floor 1 Building1 and Floor 4 South Part of No.1 Floor 1 Building 2, No.333 Hezuo Road, Hi-Tech Zone 611731 Chengdu, Sichuan Province, P.R.China

After-sales service telephone: +0086-28-60322036

E-mail: info@seamaty.com

Compilation date : Jan 26, 2024

Version：A0

seamaty

Declaration of Conformity

IVD

File No:SMTCD-DOC-24020402 Version: A0

Manufacturer: Chengdu Seamaty Technology Co.,Ltd

Address: Room 306-316 of No.1 Floor 1 Building1 and Floor 4 South Part of No.1 Floor 1 Building 2, No.333 Hezuo Road, Hi-Tech Zone 611731 Chengdu, Sichuan Province, P.R.China

SRN:CN-MF-000033937

We, the manufacturer, here with declare that the products:

Product Name: Blood gas & Electrolyte Analyzer Model: SG1 GMDN code:62181

Classification A according to Annex VIII of the Regulation (EU) 2017/746 according to rule 5.

Intended use: This product is used for quantitative determination of electrolyte content, blood gas parameters and metabolite content in blood and body fluid in vitro.

Analyte: K^+、Na^+、Cl^-、Ca^{2+}、pH、pCO_2、pO_2、Hct、Glu、Lac

Applied Standards:

EN61010-1: 2010+A:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

EN 61010-2-101:2018 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

EN 61326-1: 2020 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

EN 61326-2-6: 2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

EN ISO 13485: 2016 Medical devices — Quality management systems — Requirements for regulatory purposes

EN 13612: 2016 Performance evaluation of in ivtro diagnostic medical devices

EN ISO14971: 2019 Medical devices —Application of risk management to medical devices

EN ISO 15223: 2021 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

EN ISO 18113-01: 2013 In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements

We declare on our own responsibility that the above-mentioned product meets all the provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in virto diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU(IVDR),which apply to it.

Conformity assessment procedure: Annex II and Annex III.

It bears the mark CE

European Authorized Representative: MedNet EC-REP GmbH

Address: Borkstrasse 10, 48163 Münster, Germany

SRN of the Authorized Representative:DE-AR-000000002

This declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The declaration is valid for 3 years

Chengdu 2024-2-4

Place , date

Peng Ran

General manager

Legally binding signature, Function

CE Declaration of Conformity

Regarding in Vitro Diagnostic Medical Devices Directive (98/79/EC)

Manufacturer:

Name: Chengdu Polytech Biological Technology Co.,Ltd.

Address: No.333, Hezuo Road, Hi-tech Zone, 611730 Chengdu, Sichuan, China

European Representative:

Name: GRZAN GROUP SL

Address: C/ FUENCARRAL KM 29 MADRID 28004-MADRID

Product

Name: Cartridges for the Blood gas & Electrolyte analyzer（Dry Electrolyte Chemistry)

Specification:BG10、BG8、BG7、BE5、BE4、BG3

REF: MD10322、 MD10217、 MD10209 、 MD10214、 MD10323、 MD10324

Intended Use: The reagent is intended for human sample testing.

10 Blood Gas Electrolyte Biochemical items (BG10) are used for quantitative in vitro detection of the content of pH value, pCO2, pO2, K+, Na+, Cl-, Ca2+, Hct, Glu, and Lac in human whole blood;

8 Blood Gas Electrolyte items (BG8) are used for quantitation in vitro detection of the content of pH value, pCO2, pO2, K+, Na+, Cl-, Ca2+ and Hct in human whole blood;

7 Blood Gas Electrolyte items (BG7) are used for quantitative in vitro detection of the content of pH value, pCO2, pO2, K+, Na+, Cl- and Ca2+ in human whole blood;

5 Blood Gas Electrolyte items (BE5) are used for quantitative in vitro detection of the content of pH value, K+, Na+, Cl- and Ca2+ in human whole blood;

4 Electrolyte items (BE4) are used for quantitative in vitro detection of the content of K+, Na+, Cl- and Ca2+ in human whole blood;

3 Blood Gas items (BG3) are used for quantitative in vitro detection of the content of pH value, pCO2 and pO2 in human whole blood;

Classification: IVDD Others

Conformity Assessment Route: IVDD 98/79/EC Annex III

We confirm our product can meet the requirement of ln Vitro Diagnostic Medical Devices Directive (98/79/EC) and the following harmonized standards:

EN ISO 14971:2012	EN ISO 15223-1:2016	EN ISO 18113-3:2011
EN ISO 18113-1:2011	EN ISO 13485:2016	EN ISO 13612:2016

Signature: Tao Liu

Place and date issued: 05.20.2022

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

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

TÜV SÜD Product Service

Certificate

No. Q5 107895 0001 Rev. 02

Holder of Certificate: **Chengdu Seamaty Technology Co., Ltd.**
Room 306-316 of No.1 Floor 1 Building1
and Floor 4 South Part of No.1
Floor 1 Building 2, No.333 Hezuo Road, Hi-Tech Zone
611731 Chengdu, Sichuan, Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of biochemical analysis instrument , immunoassay instrument and blood gas electrolyte analyzer instrument for in vitro diagnosis**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 107895 0001 Rev. 02

Report No.: SH23171901

Valid from: 2024-04-26
Valid until: 2027-04-25

Date, 2024-03-05

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

TÜV SÜD Product Service

Certificate

No. Q5 107895 0001 Rev. 02

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Chengdu Seamaty Technology Co., Ltd.
Room 306-316 of No.1 Floor 1 Building1, and Floor 4 South Part of No.1 , Floor 1 Building 2, No.333 Hezuo Road, Hi-Tech Zone, 611731 Chengdu, Sichuan, Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

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

TÜV®

数网信认证

质量管理体系认证证书

注册号：87623Q0262R0M

兹证明

成都斯马特科技股份有限公司

统一社会信用代码：91510100052533028R

注册地址：成都高新区合作路 333 号 1 栋 1 层 1 号、2 栋 1 层 1 号

经营地址：成都高新区合作路 333 号 1 栋 1 层 1 号 306-316、2 栋 1 层 1 号四楼南区

审核地址：成都高新区合作路 333 号 1 栋 1 层 1 号 306-316、2 栋 1 层 1 号四楼南区

质量管理体系符合

GB/T19001-2016/ISO9001:2015

通过认证范围:

许可范围内的用于体外诊断的生化分析设备及免疫分析设备的研发、生产及销售

初次颁证日期：2023 年 11 月 08 日

有效期至：2026 年 11 月 07 日

本次颁证日期：2024 年 10 月 15 日

总经理：

日期：2024 年 10 月 15 日

1. 本证书有效性查询可扫描二维码
2. 同时可登陆 www.swxrz.com 查询
3. 也可登陆国家认证认可监督管理委员会官方网站 www.cnca.gov.cn 查询
4. 获证组织必须定时接受监督审核并经审核合格此证书方继续有效

公众号　　证书查询

数网信认证服务（北京）有限公司

认证机构地址：北京市朝阳区广渠路 36 号院 5 号楼 13 层 1327　电话：010-59775801　邮编：100020

Data Network Information Authentication

QUALITY MANAGEMENT SYSTEM CERTIFICATION

CERTIFICATION

Registration Number:87623Q0262R0M

This is to certify that

Chengdu Seamaty Technology Co.,Ltd

Unified Social Credit Code:91510100052533028R

Registered address: No.1 Floor 1 Building1,No.1 Floor 1 Building2,No.333 Hezuo Road, Hi-Tech Zone of Chengdu, Sichuan 611731, P.R. China

Address: Room 306-316 of No.1 Floor 1 Building1 and Floor 4 South Part of No.1 Floor 1 Building 2, No.333 Hezuo Road, Hi-Tech Zone 611731 Chengdu, Sichuan Province, P.R.China

Audit address: Room 306-316 of No.1 Floor 1 Building1 and Floor 4 South Part of No.1 Floor 1 Building 2, No.333 Hezuo Road, Hi-Tech Zone 611731 Chengdu, Sichuan Province, P.R.China

Quality management system in Accordance with

GB/T19001-2016/ISO9001:2015

Scope of certification

Research and development, production and sales of biochemical analysis equipment and immunoanalysis equipment for in vitro diagnosis within the scope of license

Date of initial certification:November 08th,2023

Expiry Date : November 07th,2026

Date of this certification:October 15th,2024

General manager: 申爱萍

Date:October 15th,2024

1.The validity of this certificate can be inquired by scanning QR code

2.Or inquiry by visiting www.swxrz.com

3.You can also visit the official website of National certification and Accreditation Administration: www.cnca.gov.cn to query.

4.Certified organization shall customize and pass surveillance audit to make this certificate continue to be valid.

official account　　Certificate query

Data network information Authentication service (Beijing) Co., Ltd

Address of certification authority:Room 1327, Floor 13, Building 5, Yard 36, Guangqu Road, Chaoyang District, Beijing

Telephone:010-67723875　　Postcode:100020

Cartridges for the Blood gas & Electrolyte analyzer （Dry Electrolyte Chemistry)

[Product Name]

Cartridges for the Blood gas & Electrolyte analyzer （Dry Electrolyte Chemistry)

[Packaging]

10PCS/BOX; 20 PCS/BOX; 40 PCS/BOX;50 PCS/BOX; 75 PCS/BOX;100 PCS/BOX.

Including blood gas electrolyte biochemistry test card (dry electrochemical method), blood gas electrolyte biochemistry composite quality control product (optional, level 1: 1×1.5mL/bottle, level 2: 2×1.5mL/bottle, level 3: 2×1.5mL/bottle), hematocrit (Hct) quality control product (optional, level 1: 1×1.5mL/bottle, level 2: 2×1.5mL/bottle, level 3: 2×1.5mL/bottle).

The model and test parameters of the test card are as follows:

Specification	Parameters
10 Blood Gas Electrolyte Biochemical items（BG10）	pH、pO_2、pCO_2、K^+、Na^+、Cl^-、Ca^{2+}、Hct、Glu、Lac
10 Blood Gas Electrolyte Biochemical items（BG10-N）	
8 Blood Gas Electrolyte items（BG8）	pH、pO_2、pCO_2、K^+、Na^+、Cl^-、Ca^{2+}、Hct
8 Blood Gas Electrolyte items（BG8-N）	
7 Blood Gas Electrolyte items（BG7）	pH、pO_2、pCO_2、K^+、Na^+、Ca^{2+}、Cl^-
7 Blood Gas Electrolyte items（BG7-N）	
6 Blood Gas Electrolyte items（BG6）	pH、pO_2、pCO_2、Hct、Glu、Lac
6 Blood Gas Electrolyte items（BG6-N）	
5 Blood Gas Electrolyte items（BG5）	pH、pO_2、pCO_2、Glu、Lac
5 Blood Gas Electrolyte items（BG5-N）	
4 Blood Gas Electrolyte items（BG4）	pH、pO_2、pCO_2、Lac
4 Blood Gas Electrolyte items（BG4-N）	
6 Electrolyte items（BE6）	pH、K^+、Na^+、Cl^-、Ca^{2+}、Hct
6 Electrolyte items（BE6-N）	
5 Electrolyte items（BE5）	pH、K^+、Na^+、Cl^-、Ca^{2+}
5 Electrolyte items（BE5-N）	
4 Electrolyte items（BE4）	K^+、Na^+、Cl^-、Ca^{2+}
4 Electrolyte items（BE4-N）	
3 Blood Gas items（BG3）	pH、pO_2、pCO_2
3 Blood Gas items（BG3-N）	

[Intended Use]

10 items of blood gas electrolyte biochemistry are used for in vitro quantitative detection of the concentration of potassium ion, sodium ion, chloride ion, calcium ion, glucose, lactate, pH, carbon dioxide partial pressure, oxygen partial pressure and hematocrit in human whole blood;

8 items of blood gas electrolyte are used for in vitro quantitative detection of the concentration of potassium ion, sodium ion, chloride ion, calcium ion, pH, carbon dioxide partial pressure, oxygen partial pressure and hematocrit in human whole blood;

7 items of blood gas electrolyte are used for in vitro quantitative detection of the concentration of potassium ion, sodium ion, chloride ion, calcium ion, pH, carbon dioxide partial pressure and oxygen partial pressure in human whole blood;

6 items of blood gas biochemistry are used for in vitro quantitative detection of the concentration of glucose and lactate, pH, carbon dioxide partial pressure, oxygen partial pressure and hematocrit in human whole blood;

5 items of blood gas biochemistry are used for in vitro quantitative detection of the concentration of glucose and lactate, pH, carbon dioxide partial pressure and oxygen partial pressure in human whole blood;

4 potassium ion, sodium ion, chloride ion, calcium ion, pH, carbon dioxide partial pressure and oxygen partial pressure in human whole blood;

4 items of blood gas biochemistry are used for in vitro quantitative detection of the concentration of

potassium ion, sodium ion, chloride ion, calcium ion, pH, carbon dioxide partial pressure and oxygen partial pressure in human Items are used for in vitro quantitative detection of lactic acid concentration, pH, carbon dioxide partial pressure and oxygen partial pressure in human whole blood;

6 items of electrolytes are used for in vitro quantitative detection of potassium ion, sodium ion, chloride ion, calcium ion concentration, pH and hematocrit in human whole blood;

5 items of electrolytes are used for in vitro quantitative detection of potassium ion, sodium ion, chloride ion, calcium ion concentration and pH in human whole blood;

4 items of electrolytes are used for in vitro quantitative detection of potassium ion, sodium ion, chloride ion and calcium ion concentration in human whole blood;

3 items of blood gas are used for in vitro quantitative detection of pH, carbon dioxide partial pressure and oxygen partial pressure in human whole blood;

Blood gas electrolyte biochemical composite quality control products are used for quality control of pH, carbon dioxide partial pressure, oxygen partial pressure, potassium ion, sodium ion, chloride ion, calcium ion, glucose and lactic acid items;

Hematocrit (Hct) quality control products are used for quality control of hematocrit detection.

Detecting the concentration of these substances in the blood has the following clinical significance:

1. pH (acidity): It is mainly used to monitor acid-base imbalance in clinical practice.
2. pCO2 (partial pressure of carbon dioxide): It is clinically called hypercapnia or hypocapnia when it exceeds or falls below the reference interval, and it is the main indicator for judging various types of acid-base poisoning.
3. pO2 (partial pressure of oxygen): It is clinically used as a sensitive indicator for judging hypoxia in the body.
4. K+ (potassium ion): It is clinically used as an auxiliary diagnosis for potassium metabolism disorders.
5. Na+ (sodium ion): It is clinically used as an auxiliary diagnosis for sodium metabolism disorders.
6. Cl- (chloride ion): It is clinically used as an auxiliary diagnosis for hyperchloremia or hypochloremia.
7. Ca2+ (calcium ion): It is clinically used as an auxiliary diagnosis for calcium metabolism disorders.
8. Hct (hematocrit): It is clinically increased due to blood concentration caused by various reasons, and decreased in various anemias.
9.Glu (glucose): mainly used to reflect blood sugar levels in clinical practice.
10.Lac (lactic acid): mainly used in clinical practice for auxiliary diagnosis of metabolic acidosis.

Regarding blood gas electrolyte biochemistry test cards, the commonly used detection methods include voltage method, current method and AC impedance method.

[Test Principle]

This product adopts Dry Electrochemical Method, and is mainly used for Point-of-Care Test (POCT), and can detect concentration of maximum 10 items in human samples. Reaction principles of various detection items are as follows:

1. Na + : Na + is measured by voltage method. Measure the potential difference between selective electrode and reference electrode of Na + , namely membrane potential of selective electrode of Na + , and then calculate concentration of Na + in the sample by Nernst equation;
2. K + : K + is measured by voltage method. Measure the potential difference between selective electrode and reference electrode of K + , namely membrane potential of selective electrode of K + , and then calculate concentration of K + in the sample by Nernst equation;
3. Cl - : Cl - is measured by voltage method. Measure the potential difference between selective electrode and reference electrode of Cl -, namely membrane potential of selective electrode of Cl -, and then calculate concentration of Cl - in the sample by Nernst equation;

4. Ca 2+ : Ca2 + is measured by voltage method. Measure the potential difference between selective electrode and reference electrode of Ca 2+-, namely membrane potential of selective electrode of Ca 2+ , and then calculate concentration of Ca 2+ in the sample by Nernst equation;

5. pH: pH is measured by voltage method. Measure the potential difference between pH electrode and reference electrode, namely membrane potential of pH electrode, and then calculate pH value in the sample;

6. pCO2 : pCO2 is measured by voltage method. pCO2 would produce hydrogen ions upon dissolution after entering the electrolyte layer via the surface air-permeable layer, and the hydrogen ions can change redox potential of quinhydrone in the electrolyte layer, then concentration of pCO2 can be calculated by measuring such redox potential;

7. pO2: pO2 is measured by current method. The pO2 in the blood sample enters the electrolyte layer via the surface air-permeable layer, and then forms current upon redox reaction. The current produced from pO2 is in direct proportion to dissolved pO2 concentration

8. Glu: Glu is measured by current method. Upon catalysis of glucose oxidase, Glu generates H2O2 upon oxidation. The released H2O2 has redox reaction on platinum electrode, thus generating the current in proportion to concentration of Glu in the sample.

$$\beta\text{-D-Glu} + H_2O + O_2 \xrightarrow{\text{Glucose oxidase}} \text{D-Glucose acid} + H_2O_2$$

$$H_2O_2 \longrightarrow O_2 + 2H^+ + 2e^-$$

9. Lac: Lac is measured by current method. Upon catalysis of lactate oxidase, Lac generates H2O2 upon oxidation. The released H2O2 has redox reaction on platinum electrode, thus generating the current in proportion to concentration of Lac in the sample.

$$\text{L-Lactate} + O2 \xrightarrow{\text{Lactate oxidase}} \text{Pyruvate} + H2O2$$

$$H_2O_2 \longrightarrow O_2 + 2H^+ + 2e^-$$

10. HCT: HCT is measured by AC impedance method, and its conductivity is in inverse proportion to HCT

11. Reference solution: mainly used as a basic reference for pH, Na+, K+, Cl-, Ca2+, pCO2, pO2, Glu, and Lac test items. The reference solution and the sample to be tested react electrochemically with the electrodes in turn to obtain the electrochemical parameter values of each item in the reference solution and the sample to be tested. The two sets of electrochemical parameter values for the same item are calibrated and compared to finally obtain the results of each item in the sample to be tested.

[Main Components]

1. The kit contains an independently packaged test card, a blood gas electrolyte biochemistry composite quality control product (optional), a hematocrit (Hct) quality control product (optional) and a product manual; there is a QR code on the test card, which contains calibration data, project parameters, production batch and other information.

1) Blood gas electrolyte biochemistry test card (dry electrochemical method)

Items	Main component	content
Ca^{2+}	N-(2-Hydroxyethyl)iminodiacetic acid	0.44% ~ 0.49%
	Calcium ionophore II	0.87% ~ 1.04%
Cl^-	Potassium chloride (KCl)	0.68% ~ 0.72%
	Methyltrioctyl ammonium chloride	7.81% ~ 13.60%
Glu	Glucose oxidase	0.05% ~ 0.35%
K^+	Sodium chloride (NaCl)	0.60% ~ 0.86%
	Valinomycin	0.41% ~ 0.81%
Lac	Lactate oxidase	0.111% ~ 0.222%
Na^+	Potassium chloride (KCl)	0.77% ~ 0.94%
	Sodium ionophore III	0.42% ~ 0.45%
pCO_2	Quinhydrone	0.23% ~ 0.28%
	Carbonic anhydrase	0.069% ~ 0.080%
pH	Potassium chloride	0.74% ~ 0.82%

	(KCl)	
	Trilaurylamine	3.68% ~ 4.43%
pO_2	Sodium chloride (NaCl)	0.32% ~ 0.44%
Hct	4-Hydroxyethylpiperazineethanesulfonic acid (HEPES)	2.50% ~ 3.00%
Reference solution	4-Hydroxyethylpiperazineethanesulfonic acid (HEPES)	10 ~ 18 mg/mL
	Sodium chloride (NaCl)	5.0 ~ 5.3 mg/mL
	Potassium chloride (KCl)	0.354 ~ 0.384 mg/mL
	Calcium chloride dihydrate	0.294 ~ 0.324 mg/mL
	Sodium carbonate	2.76 ~ 3.39 mg/mL
	β-D-Glucose	0.86 ~ 1.06 mg/mL
	L-Lactic Acid	0.152 ~ 0.194 mg/mL

2. The quality control products in this product are used for the original registered products and can be sold separately. There are certain differences in the target values of quality control products of different batches. The specific target values are shown in the target value sheet attached to the product.

3. K+, Na+, Cl-, Ca2+ in this product are traceable to the national standard substances GBW(E)090794 and GBW(E)090795; Glu is traceable to the national standard substance GBW(E)091004; Hct, Lac, pO2, pCO2, pH are traceable to the enterprise reference products.

[Storage Conditions & Shelf Life]

models	**Storage Condition and Shelf Life**
Blood gas 3 items, electrolyte 4 items, electrolyte 5 items, electrolyte 6 items, blood gas biochemistry 4 items, blood gas biochemistry 5 items, blood gas biochemistry 6 items, blood gas electrolyte 7 items, blood gas electrolyte 8 items, blood gas electrolyte biochemistry 10 items	Store at 2℃ ~ 8℃, valid for 12 months. The test card should be restored to room temperature (10℃ ~ 30℃) before use. Use immediately after opening (no more than 1h). Store at 10℃ ~ 30℃, valid for 7 months, use immediately after opening.
Blood gas electrolyte biochemistry composite quality control products, hematocrit (Hct) quality control products	Store at 2℃ ~ 8℃, the shelf life is 12 months. The quality control product should be restored to room temperature (10℃ ~ 30℃) before use and should be used immediately after opening.

Note:

1. After receiving the test kit, the client should select the storage method according to the above test card and quality control product storage conditions.
2. The test kit should be stored without heavy pressure and should be protected from moisture, light and heat.
3. The storage method and validity period of the test card have been determined before leaving the factory, and the client cannot change it at will during use.

[Applicable instruments]

Blood gas & electrolyte analyzers SG1, SE1 produced by Chengdu Seamaty Technology Co., Ltd.

[Sample requirements]

1. Anticoagulated whole blood without bubbles and clots. The blood collection operation should be standardized to avoid hemolysis.
2. The blood collection device includes a syringe, capillary tube and micro-tube. It is recommended to use a professional arterial blood gas needle. If there is no blood gas needle, it is recommended to use a heparin anticoagulant with less impact on the test. It is recommended to use a larger capacity blood collection device to ensure that there are enough samples for testing.

Applicable test card models	Add minimum sample volume
BG10-N 、 BG8-N 、 BG7-N 、 BG6-N 、 BG5-N 、 BG4-N 、 BE6-N 、 BE5-N 、 BE4-N、BG3-N	1mL syringe can draw at least 500μL
	2mL syringe can draw at least 800μL
	5mL syringe can draw at least 1.5mL
BG10、BG8、BG7、BG6、BG5、BG4、BE6、BE5、BE4、BG3	100μL

3. The sample should be tested immediately after collection. If it cannot be tested in time, the sample should be stored in water at 0℃～4℃ and tested within 1 hour.

4. It is recommended to use fasting blood sample for Glu testing.

Note:

1. When collecting samples, ensure that the remaining sample volume in the blood collection device is not less than its minimum sample volume.

2. If a syringe is used to insert the test card injection port, blood must be collected using heparin anticoagulation first.

[Testing method]

1. Equipment preparation

Matching blood gas electrolyte analyzer, test card, pipette or syringe, and pipette tip.

2. Operation steps

1) Turn on the analyzer and preheat according to the analyzer manual.

2) Remove the test card that has returned to room temperature and lay it flat.

3) Add an appropriate amount of sample to be tested according to different test cards.

4) Place the test card with the sample in the test card slot.

5) Enter the sample information according to the instrument manual, and the instrument will test and print the results.

6) Special attention during the test process:

a. To avoid cross contamination, the same pipette tip or syringe cannot be reused to absorb multiple samples.

b. When adding samples, ensure that the sample is completely inside the test card, otherwise it may cause abnormal testing process.

c. If a test card without N model is used, cover the sealing cover of the test card after adding samples.

d. If you use a test card with N model and use a syringe to collect samples, you should discard the first two drops of blood, then rub the syringe with both palms and gently turn it upside down several times to fully mix the sample. After removing the needle of the syringe, insert the syringe horizontally into the sample injection port of the test card.

e. After adding the sample to the test card, it should be tested immediately on the machine. Before the test card is tested on the machine, avoid excessive tilting and intentional shaking.

f. If there are foreign objects and stains on the surface of the test card, it may affect the accuracy of the test results. Avoid contaminating the test card during operation. It is recommended to wear powder-free gloves.

g. If the independent packaging of the test card is damaged before use, or the test card is found to be broken after unpacking, it cannot be used for testing, otherwise it may cause abnormal testing process and even damage the analyzer.

h. When the product exceeds the validity period, it will not be able to be tested.

3. Test parameters: During the test process, the reaction temperature is 37±0.2℃ (see the analyzer manual for details), and the test time is 4 minutes.

4. Calibration procedure

No calibration is required, the analyzer automatically reads the calibration information in the QR code on the test card.

5. Quality control procedure

When testing clinical samples, the test card should be used to test the quality control products, and the measured values should be within the specified range. It is recommended to use the blood gas electrolyte composite quality control products and hematocrit (Hct) quality control products produced by our company, take out the quality control products from the packaging box,

and place them at room temperature (10℃ ~ 30℃) to balance their temperature with room temperature. If oxygen is measured, the blood gas electrolyte composite quality control products need to be placed at room temperature for at least 4 hours. If oxygen is not measured, it only needs to be placed at room temperature for 30 minutes. It is recommended that quality control products should be tested in the following situations:

1) Before the first test of the day;
2) When laboratory conditions change;
3) When changing product batches.

6. Calculation of experimental results

The instrument has a built-in calculation function, which automatically calculates each item according to the electrochemical changes, and displays and prints the test results. In addition to the 10 items tested, the analyzer will automatically display and print the content of the calculated items, a total of 27 calculated items: pH(T)、cH^+、cH^+(T) 、 pCO_2(T) 、 $cHCO_3^-$(P) 、 cBase(B)$_e$ 、 cBase(Ecf)$_c$ 、 cBase(Ecf,ox)$_c$ 、 $cHCO_3^-$(P,st)$_e$ 、 cBase(B,ox)$_e$ 、$ctCO_2$(B)、$ctCO_2$(P)、pO_2(T)、pO_2(A)、pO_2(A-a) 、 pO_2(a/A) 、 ctO_2(B) 、 RI 、 ctHb 、 pO_2(a)/FO_2(I) 、 pO_2(a,T)/FO_2(I) 、 pO_2(a/A,T) 、 pO_2(A-a,T)、RI(T)、cCa^{2+}(7.4)、Anion Gap(K^+)$_c$、sO_{2e}。

[Reference Interval]

240 whole blood samples from normal adults were sampled randomly, and then reference interval of various items was determined statistically by normal distribution method:

Item	Reference Interval
pH	Artery whole blood: 7.350 ~ 7.450; Venous whole blood: 7.310 ~ 7.410
pCO_2	Artery whole blood: 35.0 ~ 45.0 mmHg; Venous whole blood: 41.0 ~ 51.0 mmHg
pO_2	Artery whole blood: 80 ~ 105 mmHg; Venous whole blood: 35 ~ 40 mmHg
K^+	3.50 ~ 4.90 mmol/L
Na^+	137.0 ~ 147.0 mmol/L
Cl^-	96.0 ~ 108.0 mmol/L
Ca^{2+}	1.10 ~ 1.34 mmol/L
Hct	38 ~ 51 %PCV
Glu	3.90 ~ 6.10 mmol/L
Lac	0.50 ~ 1.70 mmol/L

The reference interval is subject to influence of age, gender, territory and other factors, and it is suggested that various laboratories should establish their own reference interval regarding different user populations.

[Interpretation of test results]

1. Sample hemolysis, jaundice, and lipid turbidity may interfere with the test results to varying degrees.
2. When the sample measurement value exceeds the linear range of this test card, the deviation of the test result may exceed expectations and other methods should be used for retesting.
3. When the interfering substances in the sample exceed the limit concentration in the table below, it may affect the accuracy of the test results of the corresponding items.

Item	Interfering substances and limiting concentrations
Na^+	Bromide (35 mmol/L); triglycerides (20 mmol/L); bilirubin (80 mg/dL)
Ca^{2+}	Bromide (35 mmol/L); triglycerides (20 mmol/L); bilirubin (15 mg/dL)
Cl^-	Bromide (2.5 mmol/L); salicylate (0.8 mmol/L); triglycerides (20 mmol/L); bilirubin (80 mg/dl)
Glu	Vitamin C (2.0 mmol/L); urea (84 mmol/L); triglycerides (18 mmol/L); bilirubin (60 mg/dL)
Lac	Vitamin C (2.0 mmol/L); urea (84 mmol/L); triglycerides (18 mmol/L); bilirubin (60 mg/dL)
K^+	Triglycerides (20 mmol/L); bilirubin (80 mg/dL)
pCO_2	Triglycerides (18 mmol/L); bilirubin (60 mg/dL)
pO_2	Triglycerides (20 mmol/L); bilirubin (80 mg/dL)
pH	Triglycerides (20 mmol/L); bilirubin (80 mg/dL)
Hct	Triglycerides (20 mmol/L); bilirubin (80 mg/dL)

[Limitations of Test Method]

1. Detection results of the kit are for clinical

reference only, and shall not be taken as the base for confirmed diagnosis or case exclusion independently. To achieve diagnosis purpose, such detection results shall be used in combination with clinical examination results, medical history and other examination results.

2. Whole blood anticoagulated with EDTA or sodium citrate may interfere with the detection results.

[Product Performance Index]

1. Performance indicators of Blood Gas Electrolyte Biochemical Test Card (Dry Electrochemical Method) a) Appearance: The product shall have intact components, tidy appearance and clear texts and logos, and there shall be QR code on the test card

b)Accuracy

Assay	Relative Deviation	Assay	Relative Deviation
Na^+	±3 % or ±4mmol/L	pCO_2	±8% or ±5mmHg
K^+	±3% or ±0.15mmol/L	pO_2	±15% or ±7.5mmHg
Cl^-	±3% or ±3mmol/L	Hct	±6% or ±3%PCV
Ca^{2+}	±5% or ±0.12mmol/L	Glu	±10% or ±0.33mmol/ L
pH	±0.04	Lac	±12% or±0.6mmol/L

c)Linearity

Assay	Linear Range	Correlation Factor	Deviation from Linearity
Na^+	90 ~ 180mmol/L	≥0.995	±3 % or±4mmol/L
K^+	1.5 ~ 11mmol/L	≥0.995	±3%or±0.15mmol/L
Cl^-	65 ~ 160mmol/L	≥0.995	±3%or±3mmol/L
Ca^{2+}	0.25 ~ 2.50mmol/L	≥0.995	±5%or±0.12mmol/L
pH	6.500 ~ 8.000	≥0.990	±0.04
pCO_2	10.0 ~ 150.0mmHg	≥0.990	±8%or±5mmHg
pO_2	10 ~ 425mmHg	≥0.990	±15%or±7.5mmHg
Hct	10 ~ 75%PCV	≥0.990	±6%or±3%PCV
Glu	1.1 ~ 38.9mmol/L	≥0.990	±10%or±0.33mmol/L
Lac	0.3 ~ 20.0mmol/L	≥0.990	±12%or±0.6mmol/L

d)Precision

Assay	Intra-batch Repeatability	Inter-batch Variation
Na^+	CV≤1.5% or S≤2mmol/L	R≤3% or M≤4mmol/L
K^+	CV≤1.5% or S≤0.08mmol/L	R≤3% or M≤0.15mmol/L
Cl^-	CV≤1.5% or S≤1.5mmol/L	R≤3% or M≤3mmol/L
Ca^{2+}	CV≤1.5% or S≤0.06mmol/L	R≤5% or M≤0.12mmol/L
pH	S≤0.02	M≤0.04
pCO_2	CV≤4% or S≤2.5mmHg	R≤8% or M≤5mmHg
pO_2	CV≤5% or S≤2.5mmHg	R≤15% or M≤7.5mmHg
Hct	CV≤3% or S≤1.5%PCV	R≤6% or M≤3%PCV
Glu	CV≤5% or S≤0.17mmol/L	R≤10% or M≤0.33mmol/L
Lac	CV≤6% or S≤0.3mmol/L	R≤12% or M≤0.6mmol/L

2. Quality control product performance indicators

a) Appearance: liquid with uniform color, transparency and no impurities.

b) Expected results: The quality control product is measured on the specified detection system, and the measured value should be within the specified range of the batch.

c) Uniformity: ≤10%.

[Precautions]

1. This product is for diagnosis in vitro only. 2. The date of manufacture and expiry date of the test card are shown on the product label. 3. Both the test card and quality control are disposable, please do not reuse. 4. Since the test card contains chemical substances, therefore, it shall be used following good laboratory practices, and proper

protective measures must be taken, to avoid contact with skin and mucosa. In case of contact by mistake, please seek for medical treatment when necessary. 5. This product contains metal chip, which might have safety threat to ecological environment and human health, so it must be disposed in accordance with the legal provisions in the country and region where the test is carried out. 6. The used test card contains sample, and might have potential pathogenicity or infectiousness, so disposal must be performed according to legal provisions in the country and region where the test is carried out.

[Label Interpretation]

IVD	In vitro diagnostic medical devices		Expiration date
	Date of production		Manufacturer
	Do not reuse	LOT	Lot number
	Consult instructions for use		Temperature limitation
EC REP	EC Authorised representative	CE	Denotes conformity to specified European directives
REF	Reference Number	Σ	Contains sufficient for <n> tests

【Issued date and vision】

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