

# **Colloidal Gold Immunoassay Analyzer**

## **Instructions for use**

Read this manual carefully before use!

**Jiangsu Konsung Medical Technology Co., Ltd.**

## About this Manual

P/N: 128010379

Version: 1.0

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## Preface

Thanks for purchasing Colloidal Gold Immunoassay Analyzer (hereinafter called “**Analyzer**”) manufactured by Jiangsu Konsung Medical Technology Co., Ltd. (hereinafter called “**Konsung Medical**”).

Please keep this manual in a safe place as you may need to refer to it whilst using the analyzer.

All illustrations in this manual are for reference only. If you have any questions, please contact us.

## Conventions

- WARNING:** Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.
- CAUTION:** Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.
- NOTE:** Provides application tips or other useful information to ensure that you get the most from your product.

## Responsibility of the Manufacturer

Konsung Medical holds the rights to modify, update, and ultimately explain this manual.

Konsung Medical is responsible for the effects on safety, reliability and performance of this product, only if:

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by Konsung Medical authorized personnel;
- All the replaced components and supporting accessories that using for maintenance should be supplied or approved by our company;
- The electrical installation of the relevant room complies with the applicable national and local requirements;
- The product is used in accordance with the instructions for use.

## **FCC Caution:**

### **Part 15.21**

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

### **Part 15.19**

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

## **FCC RF Radiation Exposure Statement:**

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.
3. The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

### **Part 15.105**

**Note:** This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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## **1 Product Introduction**

### **1.1 Principles of Operation**

The Colloidal Gold Immunoassay Analyzer consists of a hand-held touch screen analyzer, and fertility and pregnancy test card manufactured by Konsung. The analyzer is designed to help you get pregnant by identifying your most fertile days each cycle. It also allows you to test for pregnancy.

The test cards are sold separately. You will need 10 fertility test cards each cycle, but may need 20 if you have a long or irregular cycle.

The analyzer works by detecting changes in key fertility hormones in urine - luteinising hormone (LH). It detects these changes using simple urine tests.

The analyzer allows you to test for pregnancy, by detecting the pregnancy hormone, HCG, in your urine.

The user collects a sample in a container and dips the absorbent wick into the collected sample for 5-10 seconds. Once the analyzer self-calibration process is completed, insert the test card with urine sample to the analyzer's slot, a sample reaction screen appears, indicating that test is working and counting down the time to result. The test is complete after a result or an error is displayed on the screen. This occurs within 3-10 minutes of sample detection.

The released version of software is 1.0.

### **1.2 Intended Use and Contraindications**

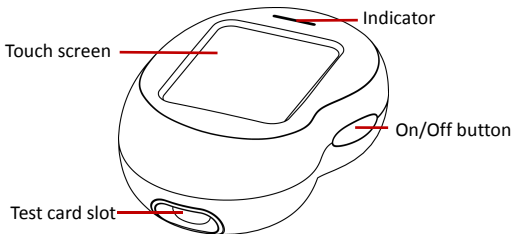
#### **Intended Use**

The Colloidal Gold Immunoassay Analyzer is intended for in vitro qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine with our HCG test card. It is also intended for in vitro qualitative detection of changes in luteinising hormone (LH) in urine with our LH test card. This test is for self-test in non-healthcare settings (such as person's home) by individuals. Only for use outside the body. For over the counter use.

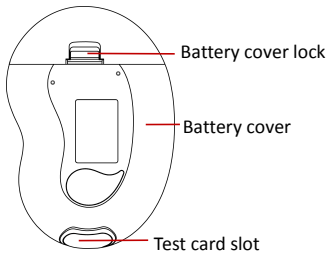
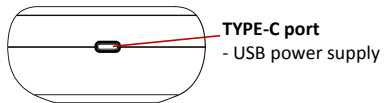
#### **Contraindications**

None

### 1.3 Knowing Your Analyzer

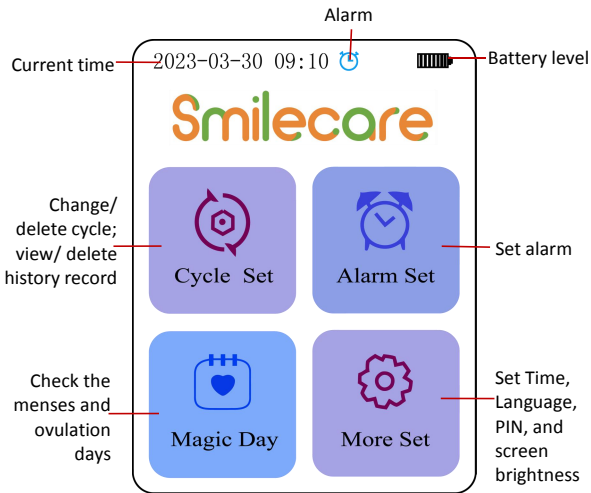


1. **On/Off Button:** press and hold this button 3 seconds to turn on or to turn off the analyzer.
2. **Test card slot:** insert test card with urine sample here.
3. **Touch Screen:** use your finger on the touch screen do not use sharp objects.
4. **Indicator:** yellow means battery low; green means connecting the USB power adapter; blue means reading the test card.



**Note:** The analyzer can be powered by two AA alkaline (LR6) 1.5V batteries (user self-purchase) or a USB adapter (connect to TYPE-C port).

## Screen display

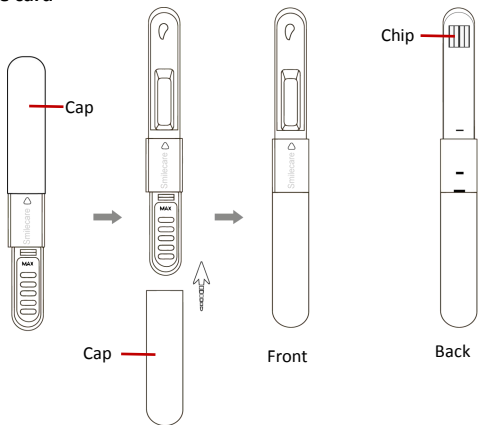


### Quick key:

- < : Return to the previous menu;
- 🏠 : Return to the Setting menu.

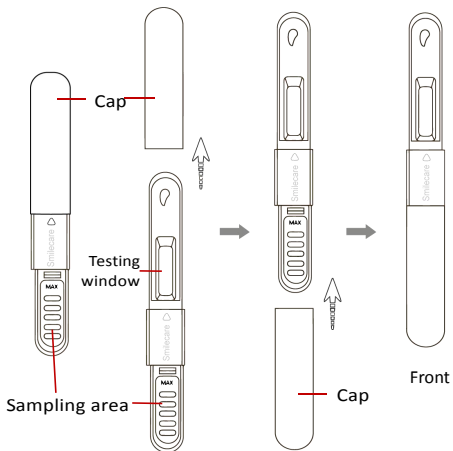


## Code card























**Note:** Insert the attached code card into analyzer to calibrate the testing item of analyzer before testing the LH or HCG. The LH code card is purple, and HCG code card is white.

## Test card



**Note: The LH test card is purple, and HCG test card is white.**

## 1.4 Symbols

Symbol	Explanation	Symbol	Explanation
	In vitro diagnostic medical device		Temperature limit
	Battery indicator		Refer to instruction manual/ booklet
	Biological risks		Caution
	Recycle		Use-by date
	Batch code		Date of manufacture
	Serial Number		Manufacturer
	Max. Stack Quantity		Atmospheric pressure limitation
	This side up		Humidity limitation
	Keep dry		Fragile, handle with care
	Non-ionizing electromagnetic radiation		The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.

## 2 Installation Procedures and Special Requirements

### 2.1 Getting Started

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier. Check all materials as per the packing list and check for any mechanical damage. If you have any questions, please contact us.

#### NOTE:

- Keep the packing material out of children's reach.
- The analyzer may be contaminated by microorganism during transport, storage and use. Verify the packaging, especially the packaging for the test card, is intact. In case of any damage, contact the carrier or our company immediately.
- Disposal of this product and its accessories and packaging (plastic bags, foam and cartons, etc.) are subject to local laws and regulations.

### 2.2 Environmental Requirements

The operating environment of the analyzer must meet the requirements specified in this manual **A.3 Environmental Specifications**.

Do not use the analyzer in places where are wet, containing corrosive gases, with strong dust, strong electromagnetic interference to ensure the normal use of it.

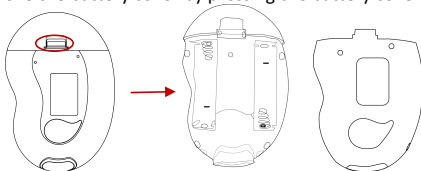
The analyzer is a precision electronic instrument that requires careful maintenance and avoids falling.

The analyzer should be placed in a dry and normal temperature environment, and placed in a well-ventilated room where is no direct sunlight, no serious dust, no strong electromagnetic interference and no corrosive gas.



## 2.3 Inserting the Batteries

The analyzer requires two AA alkaline (LR6) 1.5V batteries to operate. For optimal analyzer performance, use two new batteries that are the same brand. Do not use rechargeable batteries.

Remove the battery cover by pressing the battery cover lock.



Place the batteries according to the positive (+) and negative (-) indication. Align the + printed in the battery compartment with the + on the battery. Once both batteries are inserted replace the cover. If the batteries are not inserted correctly, the analyzer will not work.

Battery icon  Indicates that the battery works correctly. And  Indicates that the battery is low.

## 2.4 Network Safety

The operating environment is  $\mu$ Vision V5.32.0.0.

Data interface: Bluetooth transmission protocol is BLE 5.0 or above.

The software environment is embedded ARM.

User access control mechanism: user can only view measurement data on the analyzer, but cannot modify the measurement data.

## 3 Operating Instructions

The analyzer is calibrated at the factory and the user does not need to calibrate.

The analyzer is intended for home use only.

### 3.1 Powering On/Off

1. Before starting your test, you should check the analyzer for any mechanical damage.
2. Connect the adapter to the power supply socket. If you run the analyzer on battery power, ensure that the battery is sufficiently charged.
3. Press and hold **On/Off** button 3 seconds to turn on the analyzer. The analyzer screen lights on, the startup screen is displayed, and the self-test is performed.
4. Once the self-test is complete, the analyzer is ready for use.
5. Press and hold **On/Off** button 3 seconds to turn off the analyzer after finishing test.

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#### WARNING

- Do not use the analyzer if it is mechanically damaged or appears abnormal.
  - The analyzer will not turn on when battery capacity is low if battery power used only.
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### 3.2 Fertility and Pregnancy Testing

**The test card includes one instructions for use. Please read the instructions carefully before starting the test.**

Allow the analyzer and specimen to equilibrate to room temperature (10-30°C) prior to testing.

Make sure you use the correct test depending on whether you are testing for fertility or pregnancy. Insert the attached code card into analyzer to calibrate the testing item before testing the LH or HCG. LH code card and test card are purple, and HCG code card and test card are white.

### Required analyzer and reagents

- ◆ Colloidal Gold Immunoassay Analyzer
- ◆ Code card
- ◆ Test card
- ◆ Urine container

### Testing Procedures

It is important that you do all the fertility tests as requested by the analyzer. If you miss a test the analyzer will use the information it already has stored to work out your fertility status, and you may miss identifying your peak days. If you miss a test this will be advised in the information bar the next time you switch your analyzer on. Once you have set a new cycle the calendar will display the days on which you will need to test.

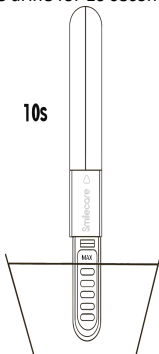
1. Press and hold **On/Off** button 3 seconds to turn on the analyzer. The analyzer enters the setting screen after completing self-test.



2. Open the foil and take the test card out and use immediately.
3. Hold the test card cap, and obtain urine sample for **10 seconds** as shown in below methods, making sure that the entire sampling area is wet.

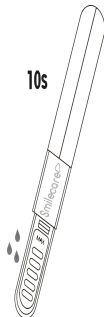
### Dipping

Collect your urine in a clean, dry container and put just the sampling area into the urine for 10 seconds.



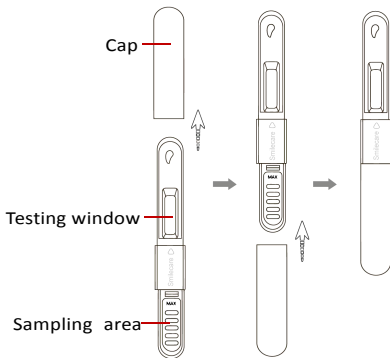
### In your urine stream

Put just the sampling area pointing downwards into your urine stream for 10 seconds.

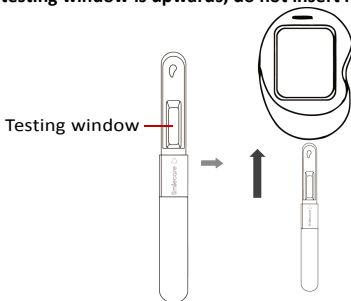


4. After the sampling, take the cap off, and place the cap over the sampling area. Wipe off any excess urine.





5. Insert the test card into the test card slot immediately. (Note: The testing window is upwards, do not insert reverse.)



6. The test countdown is displayed on the screen, and the test result is displayed on the screen after completing the test.
7. After the test is completed, remove the test card.

### Limits of test

- 1) The test card cannot be reused.

- 2) Do not use this test card past the expiration date.
- 3) Pain relievers, oral contraceptives, antibiotics, and other commonly used medications (for example) should not interfere with the test. (Studies should be performed to validate this claim.)
- 4) Certain health conditions, such as an ovarian cyst or ectopic pregnancy (pregnancy outside the uterus), can cause a false or irregular result.
- 5) The procedures should be followed precisely for accurate results.
- 6) A false negative result (negative when pregnancy exists) may occur if the urine is too dilute or with a very early stage pregnancy. If pregnancy is still suspected, retest using a first-morning urine.
- 7) For in vitro diagnostic use (not for internal use).

### **Result of LH testing**

- : indicates that it is not impossible that you will get pregnant if you have intercourse today.
- + : indicates that it is unlikely but not impossible that you will get pregnant if you have intercourse today.
- ++ : indicates you have an increased chance of getting pregnant from intercourse today. This is first displayed when the analyzer detects an increase in your estrogen level. ++ will continue to be displayed until the analyzer detects your LH surge. High is also displayed the day after your 2 Peak days. If you see more than 10 High days or more High days than you would expect.
- +++ : indicates you have reached your most fertile time, and is displayed when the analyzer detects your LH surge, 24-36 hours prior to ovulation. Have intercourse on both ++ and +++ days to maximize your chance of getting pregnant.

### **Result of HCG testing**

**Pregnant:** Your result is **“Pregnant”** and you should see your doctor who will advise you on next steps.

**Not pregnant:** Your result is “**Not pregnant**”. It may be that you are not pregnant, or if you have tested before your period is due it may be that the level of pregnancy hormone is not high enough to be detected by the test. Test again when your period is due.

**Invalid test:** It indicates that the test results will be invalid and need to be tested again.

**Note:**

- If you test on the day your period is due and the result is still “**Not Pregnant**” you may wish to test again in 3 days time. If this test gives you a “**Not Pregnant**” result and you still have not had your period, see your doctor.
- Please refer to the related test card instructions for use for result details.

### 3.3 Operational Precautions and Limitations

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#### WARNING

- Follow the instructions to use the analyzer; any improper operation may lead to inaccurate measurements.
  - The analyzer can only be used with the matched test card specified by Konsung Medical.
  - The analyzer is an in vitro diagnostic medical device designed for self-testing at home.
  - Keep out of reach of children.
  - Store your analyzer in a dry place, between 0°C and 50°C. Store your test cards in a dry place, between 4°C and 30°C.
  - There are no products available that can guarantee success in achieving pregnancy. The analyzer has been designed to assist in conception. The analyzer is not intended for contraception.
  - Do not use the analyzer near strong radiation sources. Doing so may affect the analyzer's normal operation.
  - Use only the specific power adapter. Using other adapters may result in a fire or electric shock.
  - Do not open the analyzer housing and attempt to repair it yourself. If the analyzer has fault, stop using it immediately.
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**CAUTION**

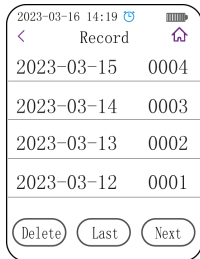
- Do not place the analyzer into the liquid, and do not put the analyzer may fall into liquids.
  - Do not place the analyzer in location that is easy to fall, falling and crashing may cause the malfunction of analyzer.
  - Do not use the analyzer if the analyzer is not working properly or has been damaged.
  - Do not place the analyzer or its data cable on the object surface with higher temperature.
  - Do not place anything on the top of the analyzer.
  - Do not service or maintain the analyzer while it is in use.
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**NOTE:**

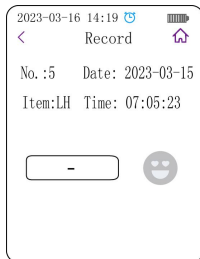
- Certain medical conditions may or may not affect the reliability of this test in predicting ovulation. These can include pregnancy, post-partum, menopause symptoms, birth control pills, some fertility medications and polycystic ovarian syndrome (PCOS). Women with medically diagnosed fertility problems should ask their health care professional if the product is suitable for them.
- Changes or modifications not expressly approved by the grantee will void the authority to operate this equipment.
- This device should not be used in locations where cellular telephone and other electronic devices are prohibited, e.g. aircraft.
- The test result is for reference only, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.
- If you test on the day your period is due and the result is still “Not Pregnant” you may wish to test again in 3 days time. If this test gives you a “Not Pregnant” result and you still have not had your period, see your doctor.
- The analyzer will automatically dim after 5 minutes if not used.
- You will be unable to turn the analyzer off while it is reading a test card.
- Do not use the analyzer in direct sunlight place, the measurement accuracy will be affected.
- Do not remove the test card or move the analyzer during testing.
- Do not leave the used test card in the analyzer's test slot.

### 3.4 Review History Record

1. In Setting screen click  → .



2. Click **“Last”** or **“Next”** to turn records page. Click **“Delete”** to delete all records.
3. Click the record to view the details of this test record.



### 3.5 Upload Measurements

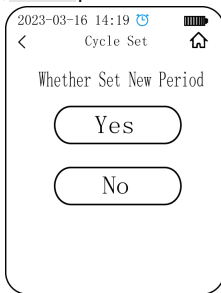
The analyzer can upload measurements to intelligent terminals via Bluetooth (only applicable for iQ2100/iQ2300 models). The upload function needs software support, please contact our service personnel and obtain the uploading details.

## 3.6 Settings

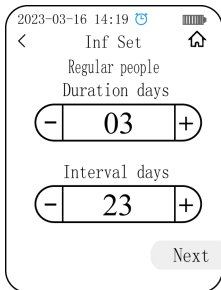
### 3.6.1 Set Your Cycle

**You need to set a new cycle when each period starts.** Set between day 3 and day 7 of your cycle, where day 1 is the first day of your period - the first day of blood flow - you should ignore spotting. If you do not set up a new cycle within the first 7 days of your cycle, you need to wait until your next cycle to use the analyzer.

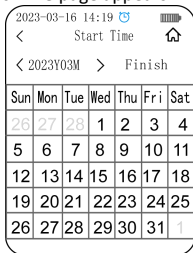
1. Click  → .



2. Click "Yes".



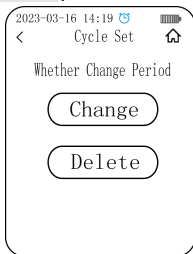
- Using + or - to adjust the days number of **Duration days** (range between 3 days to 7 days) and **Interval days** (range between 21 days to 45 days) in **Inf Set** screen.
- Click **Next**, the **Start Time** page appears.



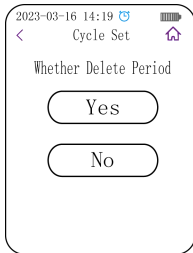
- Click your starting day, then click **Finish** to complete the cycle setting.  
**If you cannot remember when your period started or it started in the night enter the time you usually wake up. It is important to try and remember when your period started as the analyzer will work out the first day of your cycle based on this.**

### Change/Delete Cycle

- Click  → .



- Click **“Change”** to reset your duration days and interval days.
- Or click **“Delete”**.



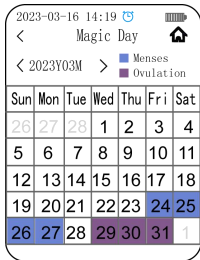
Click **“Yes”** to delete your cycle period. Click **“No”** to cancel your operation.

### Check Your Magic Day

- Set the alarm on. Refer to section **3.6.2 Set Alarm** for details.



- Click **Magic Day** to check your cycle and whether you are on a low or peak day.



Clicking **<** or **>** to view your magic days in other months.

Days in blue are your menses days in the current cycle.

Days in purple are your ovulation days in the current cycle.



### 3.6.2 Set Alarm

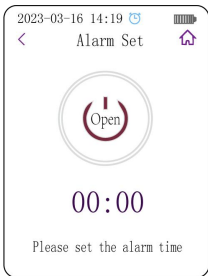
1. Press and hold **On/Off** button 3 seconds to turn on the analyzer.



2. In "**Setting**" screen, click .



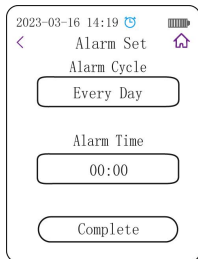
3. Click .



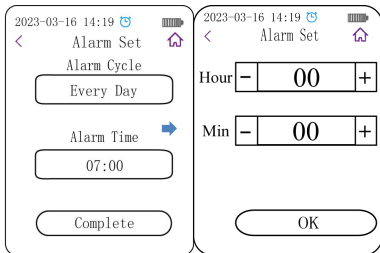
means alarm is on; means alarm is off.



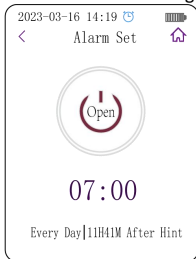
4. Click "**00:00**" to set the alarm.



5. Select alarm cycle between “**Every Day**” and “**Ring Once**”.
6. Click alarm time “**00:00**” to set the alarm hour and minute. Then click “**OK**”.



7. Click “**Complete**” to finish the alarm setting.

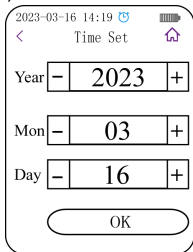


### 3.6.3 Set Time

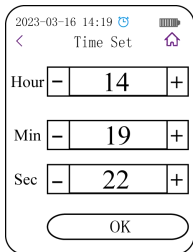
1. Press and hold **On/Off** button 3 seconds to turn on the analyzer.



2. In "**Setting**" screen, click



3. Click "+" or "-" to adjust the number of year, month and day. Then click "**OK**".

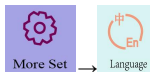


4. Click "+" or "-" to adjust the number of hour, minute and second. Then click "**OK**" to complete time setting.

### 3.6.4 Set Language

1. Press and hold **On/Off** button 3 seconds to turn on the analyzer.

- In "**Setting**" screen, click

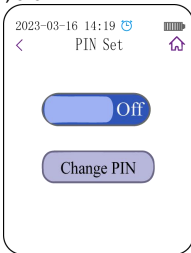


- Click "**中文**" or "**English**" to switch the language between Chinese and English.

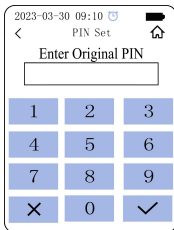
### 3.6.5 Set PIN

- Press and hold **On/Off** button 3 seconds to turn on the analyzer.

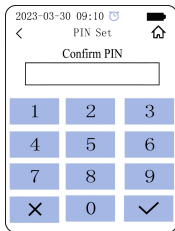
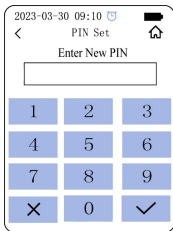
- In "**Setting**" screen, click



- Click "**ON**" or "**OFF**" to turn on or off the PIN function.
- Click "**Change PIN**" to set new PIN.

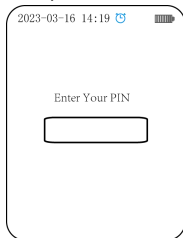


5. Enter 4 digits and click ✓. Press X to delete the wrong digit.
6. Enter new PIN and click ✓, then enter the new PIN again in “Confirm PIN” box.



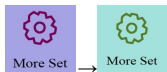
7. Click ✓ to complete the new PIN setting.

If you turn on the PIN function, you shall be asked to enter PIN after turning on the analyzer.

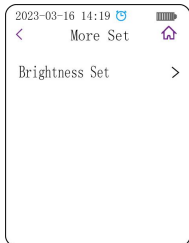


### 3.6.6 Adjust Brightness

1. Press and hold **On/Off** button 3 seconds to turn on the analyzer.



2. In "**Setting**" screen, click






3. Click "**Brightness Set**", the brightness bar appears, and touch the bar to adjust the screen brightness.



### 3.7 Upload data to APP (only for analyzer with Bluetooth module)

You can download our APP and bind your analyzer through Bluetooth connection. And then you can view your measurements on mobile.

1. Search for the keyword "**Kmilight**" or "**KS Smilecare**" in the Google Play Store or App Store (for iOS user).

2. Or scan the QR code printed in package box to obtain the download link.
3. Click the installation package to install the APP according to installation prompt. A shortcut icon  appeared on mobile after completing installation. Click  to run the APP.
4. Click the device name on homepage and select "**Immunoassay Analyzer**" in drop-down menu.
5. Click "**Start measuring by binding to the device**" and the APP will automatically search for available devices nearby. Click the searched device, a dialog box for entering the verification code pops up, enter the four digits displayed on the analyzer, then the APP will bind the selected analyzer automatically.
6. When the lipid analyzer is successfully connected, the analyzer will prompt you with "Beep", and the Bluetooth icon  will be highlighted.
7. The measurement results will be uploaded to the APP.

## 4 Care and Maintenance

The analyzer is made of highly durable materials and will withstand everyday use. Store your analyzer in a dry, safe place and take care not to drop or damage it. The analyzer is not waterproof and like any electrical equipment it must not be used if it has gotten wet.

### 4.1 Cleaning the analyzer

The analyzer should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your place, the analyzer should be cleaned more frequently.

You can use clean water to clean the analyzer surface.

1. Turn the analyzer off.
2. Clean the display screen and shell by using a soft, clean cloth dampened with clean water.
3. Dry the analyzer in a ventilated, cool place.

To avoid damage to the analyzer, follow these rules:

- ◆ Do not immerse the analyzer into liquid.
- ◆ Do not pour liquid onto the analyzer.
- ◆ Do not allow liquid to enter inside of the analyzer.
- ◆ Never use abrasive materials (such as steel wool or silver polish)

#### NOTE:

- **Keep the analyzer surface clean and do not damage the screen.**
- **The gasoline, benzene organic solvent cleaning are forbidden to use, these tests will make the analyzer deformation or paint removed and affect the performance or appearance.**
- **Any service of this analyzer can only be performed by an authorized service engineer. Do not maintain and disassembly the analyzer.**
- **Do not clean the internal parts or internal surfaces of the analyzer.**



## 4.2 Disposing of the analyzer

Remove the batteries from the analyzer and dispose of them according to the appropriate recycling protocol.

**Caution: Do not disassemble, recharge or dispose of the batteries in fire. Do not swallow. Keep away from children.**

Dispose of the analyzer according to the appropriate recycling protocol for electrical equipment. Do not dispose of electrical equipment in fire.

Discard used samples and test cards in accordance with local regulations on disposal of bio-hazard waste.

## 5 Warranty and Service

### 5.1 Service

The analyzer has a warranty period of 12 months from the date of arrival. The service or repair will be charged according to regulations when the system is out of the warranty period. Any changes or modifications to this analyzer not expressly approved by manufacturer may void your authority to operate this system.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. All faulty components can free repair or replace during the warranty period.

Do not open the analyzer's housing. If the analyzer housing is opened, the warranty will be invalid.

**To protect your rights, please keep the evidence, such as invoices, receipts and so on well and fill in the warranty card and post it to the manufacturers. The manufacturer will repair or replace the analyzer for free during its warranty period and any damage caused by non-human factors.**

### 5.2 Contact Information

If any questions in analyzer operation, please contact the manufacturer or local agency.

Jiangsu Konsung Medical Technology Co., Ltd.

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212300 Danyang Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Tel: +86-025-86181885

E-mail: info@konsung.com

## 6 Accessories and Spare Parts

**NOTE:**

- Use only the data cable and power adapter supplied or specified by Konsung.
- Disposable accessories should not be reesterilized and reused.

The following accessories and spare parts are available:

No.	Name	Qty.	Unit	Remarks
1	Colloidal Gold Immunoassay Analyzer	1	pcs	Standard configuration
2	USB cable	1	pcs	Optional
3	Qualification certificate	1	pcs	Standard configuration
4	Instructions for Use	1	pcs	Standard configuration

## 7 Troubleshooting

Some common troubles will occur during the operation of analyzer. Follow the below description to solve the troubles.

Symptoms	Potential Causes	Solution
The analyzer cannot turn on.	Battery capacity is low and no power adapter is connected.	Connect the power adapter or insert new batteries.
Date and time display error	Date and time settings are wrong	Set correct date and time by referring to the section <b>3.8.2 Set Time</b> in this manual.
Analyzer cannot perform testing	The analyzer does not work when inserting the test card.	Check the test card is inserted correctly. Insert the test card correctly.
	Analyzer is damaged.	Contact our service personnel.
The screen shows wrong characters	The screen is damaged or the processor has fault.	The analyzer needs service; please contact our service personnel for details.

## **8 Electromagnetic Compatibility**

This IVD device meets the emissions and immunity requirements of IEC 61326-2-6. The EMC countermeasures employed within the electronic instrument will provide reasonable protection against electromagnetic interference effects likely to be encountered in the home environment. The following preventive warnings apply to IEC 61326-2-6 compliant equipment.

- a) Use of this analyzer in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
- b) Do not use this analyzer in close proximity to sources of strong electromagnetic radiation (e.g. mobile phones), as these may interfere with the proper operation.

## A Product Specifications

### A.1 Analyzer Type

Electric shock protection	Class I equipment and internal powered equipment
Conducted emissions/ Radiated emissions	Group 1, Class B
Degree of protection against liquid	IPX0
Operation mode	Continuous
Operating environment	Indoor
Product expected service life	5 years
Manufacturing date	See analyzer's label

### A.2 Physical Specifications

Model	Configuration	Bluetooth Module	Dimensions	Weight
iQ2000-1	Purple main unit with USB cable	No	79mm X 115mm X 39mm (W X H X D)	About 130g (no batteries)
iQ2000-2	Green main unit with USB cable			
iQ2000-3	Purple main unit with USB cable, with batteries			
iQ2000-4	Green main unit with USB cable, with batteries			
iQ2100-1	Purple main unit with USB cable	Yes		
iQ2100-2	Green main unit with USB cable			
iQ2100-3	Purple main unit with USB cable, with batteries			

iQ2100-4	Green main unit with USB cable, with batteries			
iQ2200-1	Pink main unit	No		
iQ2200-2	Bluish white main unit			
iQ2200-3	Pink main unit with USB cable			
iQ2200-4	Bluish white main unit with USB cable			
iQ2200-5	Pink main unit with USB cable, with batteries			
iQ2200-6	Bluish white main unit with USB cable, with batteries			
iQ2300-1	Pink main unit with USB cable	Yes		
iQ2300-2	Bluish white main unit with USB cable			
iQ2300-3	Pink main unit with USB cable, with batteries			
iQ2300-4	Bluish white main unit with USB cable, with batteries			

### A.3 Environmental Specifications

Operating environment	Temperature: 10°C - 30°C; Relative humidity: 20% - 80% Barometric pressure: 86kPa - 106kPa
Storage and transportation environment	Temperature: -10°C - 50°C; Relative humidity: 10% - 90% Barometric pressure: 50kPa - 110kPa

## A.4 Technical Specifications

Measurement method	Colloidal Gold Immunochromatography
Sample	Urine
Accuracy	Relative deviation $\leq \pm 15\%$
Repeatability	Coefficient of variation(CV) $\leq 3\%$
Linearity	In the linear range of reflectance [0.20,0.80], the linear correlation coefficient (r) $\geq 0.99$ .
Stability	Relative range (R) $\leq 3\%$
Data storage	5000 records
Display screen	2.8 inch touch screen
Power adapter	input: 100V-240V $\sim$ , 50/60Hz, 0.2A; output: 5V $\text{---}$ 1.0A;
Battery	2 AA alkaline (LR6) 1.5V batteries
Port	1 TYPE-C port (cannot be used for data transmission, only for power supply)



## B Symbols and Abbreviation

### B.1 Units

Abb.	English
A	ampere
°C	centigrade
V	volt
W	watt
mg	milligram
mm	millimeter
ml	milliliter
kPa	kilopascal
h	hour
Hz	hertz
L	liter

### B.2 Symbols

Symbol	English
—	negative
%	percent
/	per; divide; or
~	to
+	positive
≤	less than or equal to
≥	greater than or equal to
©	copyright

### B.3 Terms

Abb.	Full name
AC	Alternating current
CV	Coefficient of Variation

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DC	Direct current
USB	Universal serial bus
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
LH	Luteinizing Hormone
HCG	Human Chorionic Gonadotropin

# Smilecare



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