



# **H7 Series Hemoglobin Analyzer**

## **Operating Manual**

Read this manual carefully before use the product!

Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.

## Preface

Thanks for purchasing our hemoglobin analyzer (hereinafter called “**Analyzer**”). Before using this product, please read this manual carefully for understanding the operation and maintenance of the product. Keep this manual carefully after reading, so that it can be obtained conveniently when needed.

Released version of software: 1

## About this Manual

P/N: 128010109

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## Statement

It is reminded that the product shall be used strictly complying with this manual. User’s operation failing to comply with this manual may result in malfunction or accident for which Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd. (hereinafter called **Konsung**) cannot be held liable.

Konsung holds the rights to modify, update, and ultimately explain this manual. Konsung owns the copyrights of this manual. Without prior written consent of Konsung, any materials contained in this manual shall not be photocopied, reproduced or translated into other languages.

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for

proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any questions, please contact us.

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your analyzer. If you have any questions, please contact us.

## **Intended Audience**

This manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practices and terminology as required for monitoring of critically ill patients.

## **Important Statement**

- **This analyzer can only be used with the matched microcuvette supplied by Konsung. Using the others microcuvette may cause inaccurate measurements.**
- **The hemoglobin analyzer is intended for in vitro diagnostic use only, it is indicated for use in clinical laboratories and for near patient testing.**
- **The equipment is class II equipment of protection against electric shock, Class II of overload category, class II of pollution degree.**
- **Do not disassemble or repair the analyzer at any time. If the analyzer has fault, stop using it immediately. If troubles cannot be resolved, please contact our after-sales service personnel.**
- **Do not use the equipment near strong radiation sources. Doing so may affect the equipment's normal operation.**
- **If the device is not used according to specified method by**

**the manufacturer, the protection provided by the device may be destroyed.**

- **All disposable products are not reusable.**
- **Konsung reserves the right to change the product design and specifications, subject to change without notice.**

## **Responsibility of the Manufacturer**

Konsung 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 authorized personnel;
- All the replaced components and supporting accessories that using for maintenance should be supplied or approved by Konsung;
- 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.

## **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.

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# 1 Product Information

## 1.1 Introduction

**Intended use:** The analyzer is used to determine the hemoglobin content in whole blood basing on principle of spectrophotometer.

You can quickly obtain reliable results through simple operation of the analyzer.

The working principle is as follows: place the microcuvette with blood specimen on the holder, the microcuvette serves as pipette and reaction vessel. And then push the holder to the proper position of the analyzer, the optical detecting unit is activated, the light of a specific wavelength passes through the blood specimen, and the collected photoelectric signal is analyzed by the data processing unit, thereby obtaining the hemoglobin concentration of the specimen.

Basic UDI-DI for Hemoglobin Analyzer: 693482255800JA

## 1.2 Contraindications

None

## 1.3 Components



Analyzer main unit

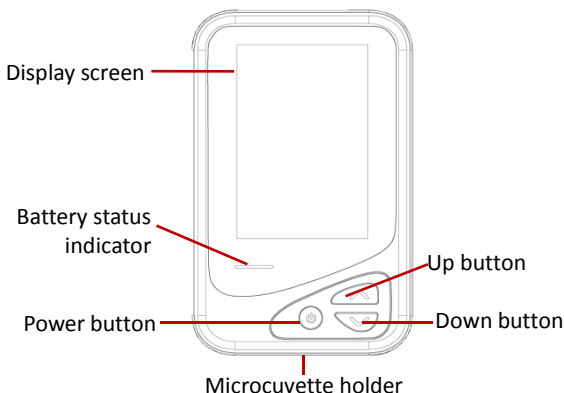


Power adapter



Data cable

### 1.3.1 Front View



Battery status indicator:

- Flashes red: indicates the battery is low capacity, charge the battery in time.
- The indicator lights red during charging;
- The indicator lights green after charging completed.

Power button

- Press and hold this button 2 seconds to turn on the analyzer.
- When the analyzer is on, press and hold this button 2 seconds to turn the analyzer off.
- When browsing the history in the main screen, press this button to return to the current result display;
- In the settings screen, press this button to confirm the settings.

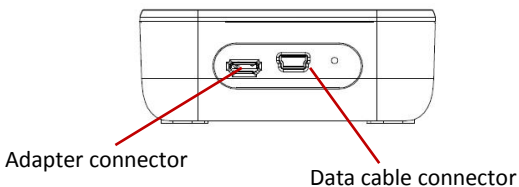
Up button:

- In the main screen, press this button to view the history forward;
- In the setting screen, press this button to select the setting item upwards.

Down button:

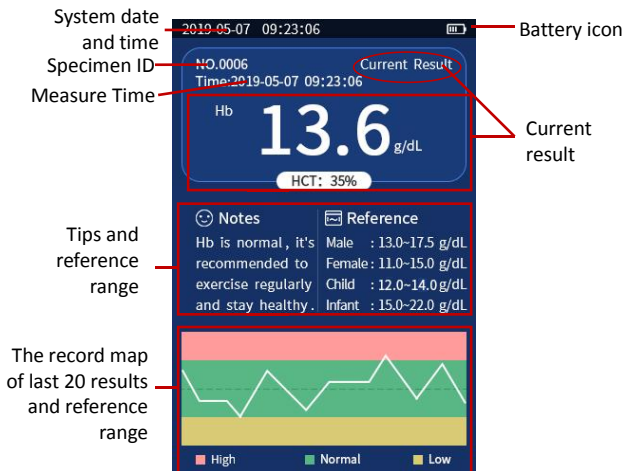
- In the main screen, press this button to view the history backward;
- In the setting screen, press this button to select the setting item backwards.
- Press the power button and down button at the same time to enter the setting interface when the analyzer is on.

### 1.3.2 Back View



## 1.3.4 Display Screen

### Main screen - Current result



## Main screen - View history record

System date  
and time

2019-05-07 09:23:06

Battery icon

NO.0006

Time:2019-05-07 09:23:06

History Result

Hb

13.6 g/dL

History  
records

HCT: 35%

Tips and  
reference

Notes

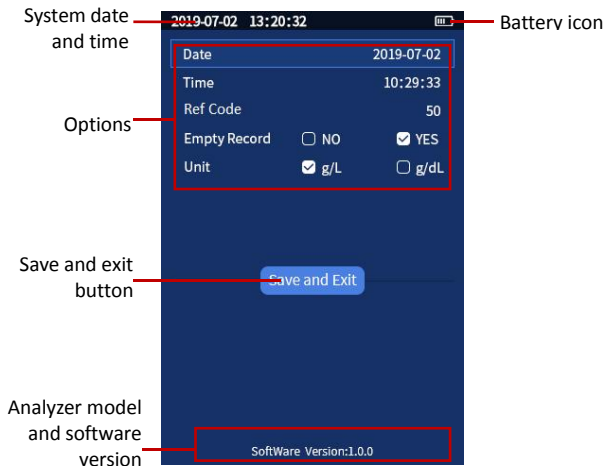
Hb is normal, it's recommended to exercise regularly and stay healthy.

Reference

Male : 13.0-17.5 g/dL  
Female : 11.0-15.0 g/dL  
Child : 12.0-14.0 g/dL  
Infant : 15.0-22.0 g/dL



## Settings Screen



## 1.4 Safety Information

### WARNING

- Before using the analyzer, you need access to professional medical knowledge.
- Follow the instructions to use the equipment, any improper operation may lead to inaccurate measurements.
- Wear protective gloves to avoid bacterial infection during operation.
- Care must be taken when dealing with blood specimen or abandoned microcuvette. Any incorrect sequence of operations is likely to lead to infection.

- **It is very dangerous for user making self-judgment or self-treatment through the measurements. Please follow the doctor's advice. Self-judgment may make the disease worse.**
  - **Use only the specific power adapter. Using other adapters may result in a fire or electric shock.**
  - **Do not leave the equipment unattended when using AC power supply.**
  - **When the analyzer is used by children, disabilities or patients, or uses the analyzer near the above person, it is necessary to monitor the analyzer closely.**
  - **Do not drop anything or put it into microcuvette holder of the analyzer, except for those items specified in this manual.**
  - **Do not use the equipment in locations where aerosol droplets or oxygen controlled.**
  - **Do not use the analyzer outdoor.**
- 
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### **CAUTION**

- **Unplug the power cord after charging the analyzer with adapter.**
- **Do not place the analyzer into the liquid, and do not put the analyzer in place where 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.**
- **To ensure user safety, use only parts and accessories specified by Konsung or in this manual.**
- **Do not use the analyzer if it is not working properly or 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.**















#### NOTE:















- The pictures and interfaces in this manual are for reference only.
- This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any questions, please contact us.

## 1.5 Symbol and Explanation

#### NOTE:

- Some symbols may not appear on your equipment.

Symbol	Explanation	Symbol	Explanation
	In vitro diagnostic medical device		Serial number
	Operating instructions		Caution
	Date of manufacture		Manufacturer
	Alternating current		Direct current
	Atmospheric pressure limitation		Humidity limitation
	Stand-by		Part Number
	Keep dry		Fragile, handle with care

Symbol	Explanation	Symbol	Explanation
	Use-by date		This side up
	Battery Status Indicator		USB connector
	Temperature limit		Batch code
	Recycle		Biological risk
	Refer to instruction manual/booklet		Warning; Biological hazard
	CE mark		Authorized representative in the European community
 Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.			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

### 2.1 Getting Started

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier.

If the packing case is intact, open the packing case in a right way, take out the analyzer and its accessories from the packing case, and check according to the Packing List. Check all materials as per the packing list and check for any mechanical damage. If you have any questions, please contact us.

Fill in the service warranty card carefully, and return it to our company, so that we can track the quality of products and supply you our service timely.

#### **NOTE:**

- **Please save the packaging materials for future transport or storage use.**
- **Keep the packing material out of children's reach. Dispose of the packaging material, observing the applicable waste control regulations**
- **The product may be contaminated by microorganism during transport, storage and use. Verify the packaging, especially the packaging for the single use accessories, 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 equipment 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.

When the analyzer is moved from one place to another, condensation may occur because of temperature or humidity difference. In this case, never start the analyzer before the condensation disappears.

The analyzer should be placed in a well-ventilated room. Place the analyzer on a clean, stable surface. Do not use the analyzer in direct sunlight or splashing places.

Do not place the device in a location where it is difficult to disconnect the power supply.

## 2.3 Connect the Power Supply

The analyzer can be powered by AC adapter or built-in rechargeable Li-ion battery.

Power requirements: AC100~240V, 20VA 50/60Hz; DC 5V, 1A

### NOTE:

- Use only the power adapter supplied or specified by Konsung.

## 2.4 Powered by Battery



The analyzer can be powered by built-in rechargeable Li-ion battery. If the AC power supply is suddenly off, the analyzer can be powered by battery.

The battery will be charged when the analyzer is connected to AC power supply.

There is a battery status indicator on the analyzer. When the battery is charged, the indicator lights red; when the battery is low, the indicator flashes red, charge the battery in time.

When the battery is working normally, the indicator is off.

Battery icons' explanations are as follows:

-  Indicates that the batteries work correctly. The solid portion represents the current charge level of the batteries in proportion to their maximum charge level.
-  Indicates that the battery is low. Please charge it in time.

The performance of the rechargeable batteries may deteriorate over time. The operating time of the batteries reflects their performance directly. If the operating time of the battery is noticeably shorter than that stated in the specifications, replace the battery or contact service personnel.

### NOTE:

- **Do not charge the battery separately with other charger.**
- **Charge the battery with power adapter supplied or specified by Konsung.**
- **It is recommended that you charge the battery within 2**


**months to ensure proper use of the analyzer if long period no use of it.**

- **Ensure that the battery has enough capacity in measurement, lower capacity may lead to inaccurate results.**
- **The operating time depends on the configuration and operation. For example, testing repeatedly will also shorten the operating time of the batteries.**

## 3 Operation of Analyzer

The analyzer is calibrated at the factory and the user does not need to calibrate. The analyzer is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Any operations of the analyzer by unauthorized or untrained person are prohibited.

### 3.1 Powering On

1. Before you start to make measurements, check the analyzer for any mechanical damage and make sure that accessories are properly connected.
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 button  3 seconds to turn the analyzer on. The analyzer screen lights up, and the startup screen is displayed, and the self-test is performed.
4. The analyzer displays the main display after finishing the self-test.

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### Warning

- **Do not use the analyzer if it is mechanically damaged or appears abnormal. Contact our company or our service personnel.**
  - **The analyzer will not turn on when battery is low if battery power used only.**
- 
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## Quality Control

The analyzer has an internal electronic self-test. Every time the analyzer is turned on, it will automatically verify the performance of the optronic unit of the analyzer. This test is performed periodically if the analyzer remains switched on. Upon passing the self-test, the display will show a flashing dash, indicating that the analyzer is ready to perform a measurement. An error code will be displayed if the self-test fails.



A special test card for quality control test is provided by Konsung, refer to the instructions for use of special test card for details. If you have any questions, please contact us.

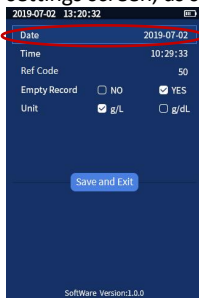
## 3.2 Powering Off













Press and hold button  3 seconds to turn the analyzer off.

## 3.3 Analyzer Settings




### 3.3.1 Set Date

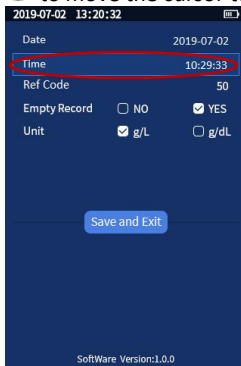
1. In main screen, press button  and  at the same time to enter the settings screen, as shown below.















2. Press button  to enter date settings and the cursor will flash on the year.
3. Press button  or  to select numbers, and then press power button  to confirm the setting. And the cursor will flash on the month.
4. Press button  or  to select numbers, and then press power button  to confirm the setting. And the cursor will flash on the day.
5. Press button  or  to select numbers, and then press button  to confirm the setting.
6. Press button  to move the cursor to **[Save & Exit]**, press button  to save settings and exit the settings screen.



### 3.3.2 Set Time

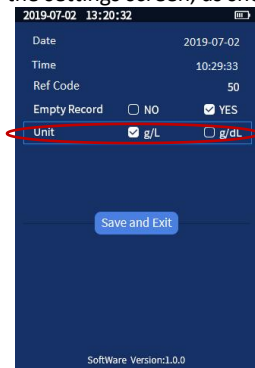
1. In main screen, press button  and  at the same time to enter the settings screen, as shown below.
2. Press button  to move the cursor to **[Time]**.










3. Press button  to enter time settings and the cursor will flash on the hour.
4. Press button  or  to select numbers, and then press button  to confirm the setting. And the cursor will flash on the minute.
5. Press button  or  to select numbers, and then press button  to confirm the setting. And the cursor will flash on the second
6. Press button  or  to select numbers, and then press button  to confirm the setting.
7. Press button  to move the cursor to **[Save & Exit]**, press button  to save settings and exit the settings screen.



### 3.3.3 Set Unit

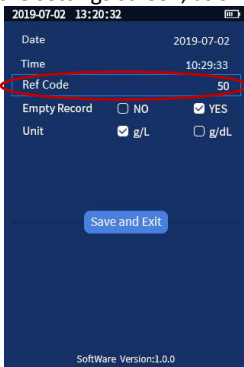
1. In main screen, press button  and  at the same time to enter the settings screen, as shown below.










2. Press button  to move the cursor to **[Unit]**.
3. Press button  to confirm setting.
4. Press button  or  to select unit “**g/L**” or “**g/dL**”. Press button  to confirm the setting.
5. Press button  to move the cursor to **[Save & Exit]**, press button  to save settings and exit the settings screen.



### 3.3.4 Set Ref Code of Microcuvette

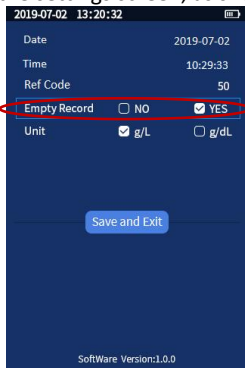
1. In main screen, press button  and  at the same time to enter the settings screen, as shown below.










2. Press button  to move the cursor to **[Ref Code]**.
3. Press button  to confirm setting.
4. Press button  or  to set Ref Code of microcuvette. Then press button  to confirm the setting.
5. Press button  to move the cursor to **[Save & Exit]**, press button  to save settings and exit the settings screen.

### 3.3.5 Clear History Record

1. In main screen, press button  and  at the same time to enter the settings screen, as shown below.



2. Press button  to move the cursor to [Empty Record].
3. Press button  to confirm setting.
4. Press button  or  to select "NO" or "YES". Press button  to confirm the setting.
5. Press button  to move the cursor to [Save & Exit], press button  to save settings and exit the settings screen.

## 3.4 Testing

### Required equipment and accessories

- ◆ Hemoglobin analyzer
- ◆ Micropipettor
- ◆ Lancet (collecting capillary specimen)

- ◆ Pipette or other transfer devices (collecting venous specimen)

### Operating restrictions

- 1 **Measurement must be carried out within 1 minute when the microcuvette filled with specimen.**
- 2 **Do not remeasure the filled microcuvette.**
- 3 **Fill the microcuvette in one continuous process. Do not refill. Wipe off excess blood from the outside of the microcuvette with a clean, lint-free wipe, being careful not to touch the open end of the microcuvette, which could result in blood being drawn out of the microcuvette.**

### CAUTION:

- **Always handle blood specimens with care, as they might be infectious. Always wear protective gloves when handling blood specimens.**
- **Do not use the analyzer if the ambient temperature too high or too low.**
- **Do not use the analyzer in direct sunlight place, the measurement accuracy will be affected.**
- **Do not move the microcuvette holder and the analyzer during measuring.**

### 3.4.1 Measuring Capillary Blood

1. Turn on the analyzer, and pull out the microcuvette holder.
2. Make sure the patient's hand is warm and relaxed. Use only the middle or ring finger for sampling. Avoid fingers with rings on.



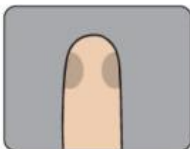
3. Clean fingertip with disinfectant and allow drying completely or wiping off with a dry lint-free wipe.



4. Using your thumb, lightly press the finger from the top of the knuckle towards the tip. This stimulates the blood flow towards the sampling point.



5. For best blood flow and least pain, sample at the side of the fingertip, not in the center.



6. While applying light pressure towards the fingertip, puncture the finger using a lancet \*.



**\* The depth of spring type lancet is at least 2mm, preferentially produce enough blood.**

7. Wipe away first drop of blood.



8. Re-apply light pressure towards the fingertip until another drop of blood appears.




9. When the blood drop is large enough, fill the microcuvette in one continuous process. Do not refill.



10. Place the filled microcuvette in the microcuvette holder. This must be performed within ten minutes after filling the microcuvette. And gently push the microcuvette holder back into the measuring position.

11. The hemoglobin value of the sample is displayed after finishing testing.

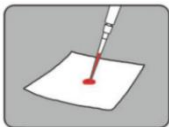
**NOTE:**

- Icon “**3.4.2 Measuring Venous Blood**

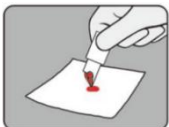
1. If the blood sample stored in the refrigerator, it should be preceded and heated to room temperature (5-35°C, 41-95°F) before measuring. Using a mechanical stirrer to stir the sample at least 1-2 minutes or using hand to upside down 10-20 times of the sample tube to make the venous blood samples was thoroughly mixed.



2. Place a drop of blood onto a hydrophobic surface, e.g. a plastic film, using a pipette or a suitable blood transfer device.





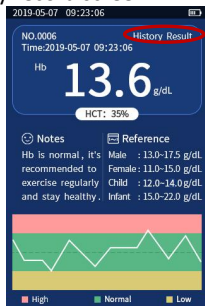
3. Fill the microcuvette in one continuous process. Do not refill.







4. Place the filled microcuvette in the microcuvette holder. This must be performed within ten minutes after filling the microcuvette. And gently push the microcuvette holder back into the measuring position.
5. The hemoglobin value of the sample is displayed after finishing testing.

### 3.5 Review History Record

1. In the main screen, press button  or  to enter the review history record screen.



2. In this screen, press button  or  to review the previous results one by one.

**Note: In history screen, press and hold button  or  2 seconds to quickly review the records.**

## 3.6 Upload Measurements

The analyzer can upload the measurements to the desired device through the USB data cable (optional). The upload function needs software support; please contact our service personnel for details.

## 4 Care and Cleaning

Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment.

Warranty does not cover damage caused by unapproved substances or methods.

We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection.

For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist.

### 4.1 Cleaning 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 equipment should be cleaned more frequently.

Recommended cleaning agent is Ethanol (75%)

Follow the below steps to clean the main unit:

1. Turn the analyzer off.
2. Clean the display screen and shell using a soft, clean cloth dampened with neutral cleaning solution.
3. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
4. 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 or accessories.
- ◆ Do not allow liquid to enter the case.
- ◆ Never use abrasive materials (such as steel wool or silver polish)

## 4.2 Cleaning Microcuvette Holder

1. Check that the analyzer is off. The display should be blank. Pull the microcuvette holder out to its loading position.
2. Clean the microcuvette holder with alcohol or mild detergent.
3. It is important that the microcuvette holder is completely dry before pushing back to the analyzer.

### NOTE:

- **Keep the working environment and the analyzer surface clean and do not damage the screen.**
- **The gasoline and benzene organic solvent cleaning is forbidden to use, these tests will make the analyzer deformation or paint removed and affect the performance or appearance.**
- **The microcuvette holder should be cleaned after each day of use.**
- **Do not contaminate or damage the color block when cleaning the card holder.**
- **Any service of this analyzer can only be performed by an authorized service engineer. Do not maintain and disassembly the analyzer. If any quality problems occur, please call our customer service.**
- **The microcuvette holder must be kept clean to avoid affecting the accuracy of the test results.**
- **For cleaning, disinfecting and sterilizing other accessories, please contact the manufactures for details.**

### **4.3 Disinfection**

There is no part that requires user to disinfect. Disinfection may cause damage to the analyzer or accessories. We recommend that you disinfect the equipment only when necessary as determined by your hospital's servicing schedule. Clean the analyzer before disinfection.

The recommended times of disinfection is three hundred. Recommended disinfectants are Ethanol 75%, isopropanol 70%.

### **4.4 Disposal of Waste**

Discard used specimens, microcuvette and protective gloves in accordance with local regulations on disposal of bio-hazard waste.

The analyzer should be disposed in accordance with local standards for the disposal of electronic waste when after the expiry of the analyzer's life.

## 5. Warranty and Service

Refer to the product label for the manufacture date of the analyzer.

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

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. The manufacturer will repair or replace the analyzer for free during its warranty period and any damage caused by non-human factors.**

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

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## 6 Accessories and Spare Parts

### NOTE:

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

The following accessories and spare parts are available:

Accessory name/Model	Remarks
Microcuvette	Standard configuration
Power adapter	Standard configuration
Data cable	Standard configuration
USB data cable	Optional

## 7 Troubleshooting

### 7.1 Error Code

The analyzer will identify some troubles during operation, and the fault code will be displayed on the screen. Follow the below description to solve the troubles.

Prompts	Explanation	Solution
ERR:01	Sample type error	Replace the new microcuvette.
ERR:02	File read error	Contact the manufacturer.
ERR:03	POST error, LED1 aging	Restart analyzer. If trouble still exists, contact the manufacturer.
ERR:04	POST error, LED2 aging	Restart analyzer. If trouble still exists, contact the manufacturer.
ERR:05	Holder not in place	Retest and confirm that the holder is pushed into place
ERR:06	Dirty optical components	Clean the holder with a cotton swab dampened with water.
ERR:07	Microcuvette blank or unloaded microcuvette	Fill the microcuvette with blood sample and retest.
ERR:08	Holder has light blocking substances.	Check the holder and clean it if there is foreign matter.
ERR:09	High ambient temperature	Ensure that the ambient temperature is 5-35°C.
ERR:10	Low ambient temperature	Ensure that the ambient temperature is 5-35°C.

## 7.2 Other Troubles

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 AC power is connected.	Plug in the adapter and check if the power indicator is red. If it does not turn on, or it still does not start after turning on the power, please contact our service personnel.
Gently push the microcuvette holder after loading the microcuvette, and the holder does not respond.	Microcuvette holder is damaged.	Replace the new microcuvette holder.
	The microcuvette holder is blocked by foreign matter.	Remove the foreign matter from the microcuvette holder, restart the analyzer, and contact our service personnel if the trouble still exists.
	Analyzer is damaged.	Replace a new analyzer
	Battery capacity is low and no AC power is connected.	Connect to the AC power supply to charge battery and perform a new measurement.
The screen gives erroneous characters	The screen is damaged or the processor has fault.	The analyzer needs service; please contact our service personnel for details.

## 8 Electromagnetic Compatibility

1. The equipment complies with the electromagnetic compatibility requirements specified in IEC61326-1 and IEC61326-2-6.
2. The manufacturer should provide EMC information to the customer or user. The user should ensure that the equipment is in an electromagnetic compatibility environment and that the equipment is functioning properly.
3. It is recommended to evaluate the electromagnetic environment before using the equipment. Do not use the equipment near strong radiation sources. Doing so may affect the equipment's normal operation.
4. It may cause damaging electrostatic discharge, and resulting in inaccurate test results when using the equipment in a dry environment, especially in a dry environment with artificial materials (such as artificial fabrics, carpets, etc.).
5. The equipment is designed and tested according to Class A equipment of CISPR 11. The equipment may cause radio interference, protective measures are required when using in home.

**Table 1**

<b>Electromagnetic emissions</b>	
<b>Emission test</b>	<b>Compliance</b>
CISPR11 Conducted emissions	Group 1, Class A
CISPR11 Radiated emissions	
Harmonic emissions IEC 61000-3-2	Not applied
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applied

**Table 2**

Electromagnetic immunity			
Immunity test Phenomenon	Basic standard	Test value	Performance criterion
Electrostatic discharge (ESD)	IEC/EN 61000-4-2	Contact discharge: $\pm 2$ kV, $\pm 4$ kV Air discharge: $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV	B
Electromagnetic field	IEC/EN 61000-4-3	3 V/m (80 MHz to 2 GHz)	A
Electrical fast transient/burst	IEC/EN 61000-4-4	Power supply cord: $\pm 1$ kV (5/50 ns, 5 kHz)	B
Surge	IEC/EN 61000-4-5	Line to ground: $\pm 2$ kV Line to line: $\pm 1$ kV	B
Conducted RF	IEC/EN 61000-4-6	Power cord: 3V (150 kHz to 80 MHz)	A
Power frequency magnetic field	IEC/EN 61000-4-8	3 A/m (50Hz, 60Hz)	A
Voltage dips, short interruptions	IEC/EN 61000-4-11	0% during 1 cycle 40% during 10/12 cycles 70% during 25/30 cycles 5% during 250/300 cycles	B C C C
<b>Performance criterion</b>			
A. The equipment shall continue to operate as intended during and after the test.			
B. The equipment shall continue to operate as intended after the test.			
C. Temporary loss of function is allowed, provided the function is self-recoverable or can be restored by the operation of the controls.			

## A Product Specifications

### A.1 Analyzer Type

Electric shock protection	Class II equipment and internal powered equipment
Degree of protection against liquid	IPX0
Operation mode	Continuous


### A.2 Physical Specifications

Model	Configuration	Dimensions	Weight
H7-1	Main unit	130 mm x 82 mm x 31.5 mm (L x W x H)	About 210 g
H7-2	Main unit + Indicators		
H7-3	Main unit + Mini USB (TTL) + indicator		

### A.3 Environmental Specifications

Operating environment	Temperature: +5°C~+35°C; Relative humidity: ≤85%RH
Operating atmospheric pressure	70 kPa~110 kPa
Storage and transportation environment	Temperature: -20°C~+60°C; Relative humidity: 10%~90%
Storage and transportation atmospheric pressure	50 kPa~110 kPa

## A.4 Technical Specifications

Principle of measurement	Photometric detection method
Measurement range	0.0 g/L~256.0 g/L
Test Items	Hemoglobin content, HCT (calculated value)
Specimen type	Peripheral blood or venous blood
Specimen volume	≤10 μL
Test time	≤5 s
Accuracy or comparability	≤±3%
Repeatability	Within range 30 g/L to 250 g/L, CV≤1.5%
Blank counting	total amount of Hb ≤1 g/L
Data storage	2000 results can be stored
Display screen	3.5 inch TFT
Power supply	5 V  1 A /Li-iron battery 3.7 V

## B Symbol and Abbreviation

### B.1 Units

Abbreviation	Full name
$\mu\text{l}$ ( $\mu\text{L}$ )	microliter
A	ampere
$^{\circ}\text{C}$	centigrade
V	volt
W	watt
mm	millimeter
kPa	kilopascal
h	hour
Hz	hertz
L	liter

### B.2 Symbols

Symbol	Explanation
—	negative
%	percent
/	per; divide; or
~	to
+	positive
$\leq$	less than or equal to
$\geq$	greater than or equal to
©	copyright

## B.3 Terms

<b>Abbreviation</b>	<b>Full name</b>
AC	Alternating current
CV	Coefficient of Variation
DC	Direct current
TEMP	Temperature
USB	Universal serial bus
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
Hb	Hemoglobin



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