Brief Biomedical

Blood Glucose, Blood Ketone and Uric Acid Analyzer

User Manual

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1. System Overview

The Blood Glucose, Blood Ketone and Uric Acid Analyzer is designed to collect capillary whole blood samples from adult fingertips and measure the concentrations of glucose, 3-Hydroxybutyric acid (referred to as blood ketone), and uric acid in the blood, providing relevant test results.

1.1 Instrument Introduction

【Instrument Name】Blood Glucose, Blood Ketone and Uric Acid Analyzer

【Applicable Models】Golden MangoI、Golden MangoII、Golden MangoIII

【Structure and Components】

The instrument is mainly composed of micro laser blood sampling module, electrochemical detection module, control module, display module, battery, and power adapter (optional).

【Software Version】

V1

【Operating Conditions】：

a)Temperature Range: 5°C to 40°C；

b)Relative Humidity: ≤80% RH；

【Working Principle】

The Blood Glucose, Blood Ketone and Uric Acid Analyzer is designed for collecting capillary whole blood samples from adult fingertips and analyzing glucose, 3-Hydroxybutyric acid, and uric acid levels. The instrument is designed

and manufactured in compliance with medical-grade electrical safety standards and laser safety regulations. During blood sampling, a 2940 nm pulsed laser is applied to the skin tissue, creating micro-pores ranging from 0 mm to 1.2 mm. This facilitates the collection of peripheral blood samples. The collected sample can then be used with specific test strips for blood glucose (glucose oxidase or dehydrogenase method), blood ketones (electrochemical method), or uric acid (electrochemical method) to measure glucose, 3-Hydroxybutyric acid, or uric acid concentrations.

1.2 Symbol Interpretation

The following symbols are used in this manual：

	Follow Operating Instructions Note: Indicates "Refer to the User Manual" on the instrument.。
	Biohazard
	BF Type Applied Part
	In Vitro Diagnostic Medical Instrument
	Serial Number
	Batch Code
	Warning
	Manufacturer
	Caution: Electrical Shock Risk

	Temperature Limit
	Humidity Limit
	Atmospheric Pressure Limit
	Emergency Laser Shutdown
	Caution: Laser Radiation
	Class 4 Laser Product: Improper use may result in unintended damage to eyes and skin. Reference Standard: GB 7247.1-2012, "Safety of Laser Products – Part 1: Equipment Classification and Requirements". Maximum Laser Radiation Output: ≤170 mJ, Pulse Duration: 40 μs to 750 μs
	Non-Ionizing Radiation
	Separate Collection of Electrical and Electronic Equipment Complies with the "Waste Electrical and Electronic Equipment (WEEE) Directive".
	Protect from Rain
	Maximum Stacking Limit

	Class II Equipment
	Standby
IP22	Prevents intrusion of solid objects larger than 12 mm and protects against water droplets when tilted up to 15 degrees.

1.3 Package Contents

The package includes：

1.Blood Glucose, Blood Ketone and Uric Acid Analyzer

2.Charging Cable

3.Storage Case

4.User Manual (including Warranty Card)

5.Certificate of Quality Compliance

1.4 Instrument Structure

A、Structure (Figure 1 illustrates the instrument with the pull rod at the extended position)

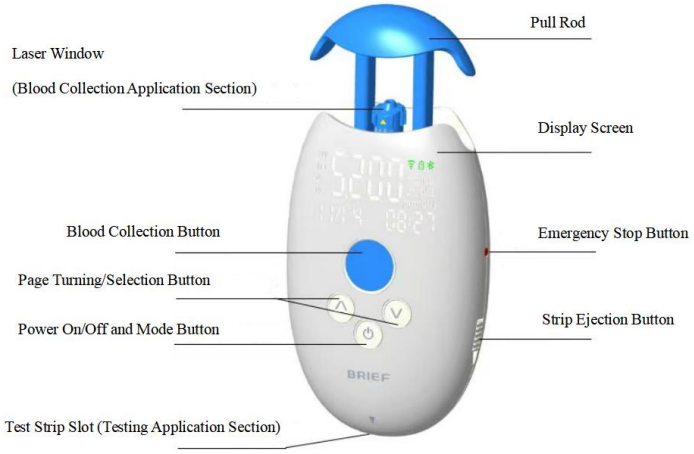


Figure 1

B、Display Screen (Figure 2 shows the instrument's display interface)

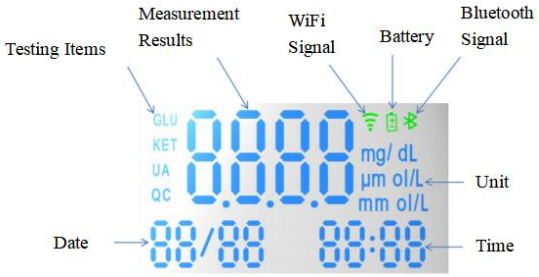


Figure 2

2. Blood Sampling and Parameter Measurement

The instrument is designed for collecting blood samples from the finger and measuring the concentrations of blood glucose, 3-Hydroxybutyric acid, and uric acid. To ensure the accuracy of the measurement process and results, please carefully review this manual and the accompanying test strip instructions before use. The following outlines the steps for blood sampling and parameter measurement.

2.1 Preparation

Gather the analyzer, alcohol swabs, and the manufacturer-specified test strips. Wash your hands thoroughly with soap, dry them completely, and disinfect the sampling site with an alcohol swab. Allow the alcohol to fully evaporate before proceeding with blood collection.

2.2Test Strip Insertion

Remove a test strip from the container (ensuring it is within its expiration date) and insert it into the test strip slot. The instrument will power on automatically. Alternatively, you can manually turn on the instrument by holding the power button for over 3 seconds before inserting the test strip. The analyzer will automatically recognize the test strip type, display it in the test project area, and provide a voice prompt confirming the test strip type.

Important Notes：

Before uric acid testing, the analyzer must first be calibrated (calibration is

not required for blood glucose or 3-Hydroxybutyric acid testing). When using a new box of uric acid test strips, calibrate the analyzer using the calibration card provided in the box. Insert the calibration card into the test strip slot and confirm that the code displayed on the analyzer matches the code on the uric acid test strip packaging. After calibration, remove the calibration card. When inserting a uric acid test strip, ensure the code displayed on the analyzer matches the code on the test strip packaging before applying a blood sample. Mismatched codes may lead to inaccurate results.

2.3Blood Sample Collection

To collect a blood sample, pull out the pull rod at the top of the instrument. When it reaches the correct position, the instrument will emit a soft "click" sound. The current laser intensity level for blood sampling will appear on the screen. Adjust the intensity level as needed by briefly pressing the selection buttons (∧ or ∨).

The laser energy can be adjusted from level 1 to 5 (with some models supporting up to 9 levels). Higher levels provide stronger laser pulse energy. For adults, it is recommended to start at level 2. For individuals aged 50 or older, or those with rough skin, starting at level 3 is advisable. If the selected level does not yield sufficient blood, gradually increase the intensity. Avoid skipping levels directly. The percentage energy output for each level is outlined in the table below::

Laser Level	Energy Output Percentage
Level 1	30%
Level 2	50%
Level 3	70%
Level 4	90%
Level 5	100%

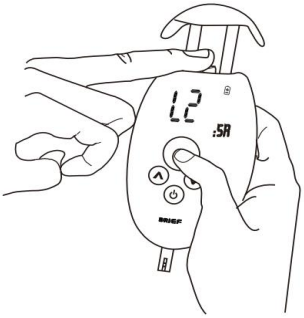


Figure 3

When the blue indicator light on the blood sampling button flashes, it indicates the laser is charging. Once charging is complete, the green indicator light will remain steady. Follow the voice prompt to press the intended blood sampling site of your finger firmly against the laser window surface (Figure 3 shows a diagram of finger blood sampling). Press the blood sampling button to activate the laser and collect the blood sample. Laser activation will produce light and sound, which is normal. Keep your finger firmly pressed against the laser window until you hear the voice prompt, "Please apply the blood sample to the test strip." Avoid moving, shaking, or withdrawing your finger during this process, as it may cause blood collection to fail.

Important Note:

1）If the pull rod is not fully extended to the correct position or the green indicator light around the blood sampling button is not illuminated, pressing the

button will not activate the lase.

2） The laser creates a very small wound. If there is no blood or insufficient blood after pressing the sampling button, gently squeeze the fingertip to increase blood flow. If repeated attempts fail to produce blood, refer to Chapter 6 of this manual for additional guidance.

3）Always discard the first drop of blood and use the second drop for testing.

4）Immediately apply the blood sample to the designated end of the test strip. Prolonged exposure to air may lead to inaccurate results or coagulation, making sampling difficult or impossible.

2.4Parameter Measurement

Position the sample end of the test strip at the wound to collect the blood sample. Hold the test strip at an angle of 0º–40º to the finger for optimal blood absorption (see Figure 4 for an example of blood glucose sampling). Once the instrument emits a prompt sound and starts the countdown, you can remove your finger. After the countdown ends, the instrument will display the test results. You can also use the navigation buttons (up/down) to review previous test results. After the measurement is complete, remove the test strip manually or use the eject button to discard it.

To conduct a new test, insert a new test strip for the desired parameter. Allow the analyzer to recognize the test strip type, then proceed with the testing steps as described earlier. Before applying the blood sample, clean any residual blood from the previous test using a cotton swab. Squeeze the finger again to produce

an adequate blood sample for the new test. If the sample is insufficient, repeat the blood sampling process. Required Blood Sample Volumes: Blood Glucose: 0.5 μL Uric Acid: 1.5 μL .Blood Ketones: 0.8 μL.

Important Notes：

The following conditions may result in inaccurate measurement results:

a)The blood drop does not completely fill the reaction area (insufficient sample volume)；

b)The blood absorption process on the test strip is not continuous；

c)The blood sample is exposed to air for an extended period before testing；

d)Non-compatible or expired test strips are used；

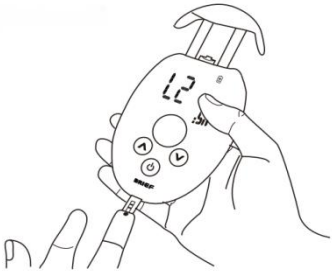


Figure 4

3. Instrument Functions

3.1 laser blood collection

The instrument uses a single-pulse laser to create a micro-pore at the sampling site, enabling quick and efficient blood collection. For detailed operating instructions, refer to Chapter 2.

3.2 Blood Glucose, Blood Ketone, and Uric Acid Testing

Using manufacturer-specified test strips for blood glucose, 3-Hydroxybutyric acid, or uric acid, the instrument measures the concentrations of these parameters in capillary whole blood samples from the fingertip. After testing, the instrument displays the test type, result, unit, and test date. Detailed instructions are provided in Chapter 2.

3.3 Data Management

3.3.1 Data Storage

The instrument can store up to 10,000 historical test records, encompassing all test parameter results, including quality control measurements.

3.3.2 Data Review

To review historical measurements, turn on the instrument and use the navigation buttons (∧ or ∨). If the instrument is in laser blood collection mode (see Chapter 2), press the mode button to switch to test mode and access past results.

3.3.3 Data Transfer

After powering on the instrument, connect it to a terminal instrument through network pairing. Once successfully paired, conduct the parameter test. The results will be automatically transmitted to the connected terminal instrument.

3.4 Emergency Stop Function

If the instrument encounters an abnormal condition or specific situation while powered on, the user can press the red emergency stop button on the right side of the instrument to immediately disable the laser blood collection function, ensuring safety. Once the issue is resolved or the instrument is ready for use, the laser function can be reactivated by restarting the instrument or pressing the mode button twice in quick succession.

3.5Calibration Function

3.5.1When to Perform Quality Control Tests

The analyzer is pre-calibrated at the factory. However, quality control testing is recommended under the following conditions to confirm the proper functioning of the instrument, test strips, and operational accuracy:

a)When using a new box of test strips；

b) If the test strip container was not properly sealed；

c)If you want to verify the performance of the analyzer and its test strips；

d)If the test strips were stored in conditions exceeding permissible humidity or temperature limits;

e)If the instrument has been dropped;

f)If test results are inconsistent with how you feel;

g) If you want to confirm the accuracy of your operation steps;

3.5.2 Quality Control Solution Guidelines

When using the quality control solution for testing, ensure the following conditions are met:

a)Only use the manufacturer-designated quality control solution compatible with the instrumen;

b)The testing temperature for the quality control solution must be between 10°C and 40°C;

c)Shake the quality control solution thoroughly before use (shake for 2–3 minutes by hand);

d)The shelf life of the solution depends on storage conditions and whether the bottle has been opened. Refer to the quality control solution instructions for details;

e)Ensure the bottle cap is securely tightened after use;

3.5.3 Testing Procedure

Select the appropriate quality control solution and open the bottle. Discard

the first two drops, then squeeze a sufficient amount onto a clean, flat, non-absorbent surface. Insert the test strip into the instrument (for uric acid test strips, perform code calibration first, as explained in Section 2.2). Gently touch the sample end of the test strip to the quality control solution. Once the instrument begins the countdown, it indicates that an adequate amount of solution has been absorbed by the strip. When the countdown is complete, the quality control test result will be displayed on the screen.

The acceptable test range for each concentration of the batch-specific quality control solution is printed on the label of the test strip container or packaging. If the system is functioning properly, the test result should fall within the specified range.

3.5.4 Result Interpretation

If the quality control results are outside the acceptable range, take the following steps to address the issue:

Troubleshooting Checklist	Recommended Actions
Verify the expiration date of the test strips and quality control solution.	Discard test strips or quality control solution if they have exceeded their expiration date or the solution's open-use period.
Ensure any residual liquid on the bottle cap of the quality control solution is wiped with a tissue before and after use.	Wipe the bottle cap with a tissue, then use a fresh test strip and a new drop of quality control solution to repeat the test.

Confirm that the test strip container lid and quality control solution bottle cap are tightly sealed at all times.	Replace test strips or quality control solution if they have been exposed to air for an extended period.
Check if the test strips were exposed outside the container for an extended period.	Perform the quality control test with a new test strip.
Ensure the test strips and quality control solution were stored in a cool, dry place.	Ensure test strips and quality control solution are stored correctly in a cool, dry environment.
Confirm that the quality control test was performed according to the required testing procedure.	Revisit the "Quality Control Solution Guidelines" and "Testing Procedure" sections, then repeat the test following the correct steps.
Verify that the quality control results were correctly matched with the appropriate test range and corresponding solution concentration during interpretation.	Ensure the concentration of the quality control solution matches the specified test range before interpreting the results.
If you still have questions or concerns	Perform the test with a new test strip.

If the issue persists after troubleshooting steps are followed, please contact your distributor for further assistance or to request a replacement instrument.

Important Notes : The quality control solution is not included as a standard component of the product. To conduct quality control testing, please purchase it from our authorized distributor.

3.6 Prompt Features

The instrument provides user guidance through components such as a voice player, indicator lights, and display screen, ensuring ease of operation for all

functions. Detailed descriptions are as follows:

3.6.1 Error Alert

If an error occurs during blood sampling or measurement, the display screen will show an error message. The instrument cannot be used again until the issue is resolved (refer to Section 6 for details).

3.6.2 Battery Indicator

Normal Battery Level: The battery icon on the display appears green. Low Battery Level: The battery icon turns red. To ensure uninterrupted operation, recharge the instrument promptly when the red indicator appears. Auto Shutdown: To conserve power, the instrument will automatically shut down after extended periods of inactivity.

3.6.3 Charging Indicator

While charging, the battery icon on the display blinks in a regular pattern. Once fully charged, the icon becomes solid green.

Note: The instrument must remain powered off during charging.

3.6.4 Voice Prompt

Upon powering on, the instrument provides voice prompts to assist users in completing necessary operations with ease.

3.6.5 Network Indicator

When powered on, the Wi-Fi and Bluetooth icons on the display reflect the current network status. During network setup, the icons flash; after a successful

connection, they remain solid; in all other cases, the icons are off.

4. System Settings

When the instrument is powered on for the first time, users can configure parameters such as the date, time, and blood glucose units based on their preferences. To start the setup process, press and hold both the left and right selection buttons for more than 3 seconds. After the initial setup, users can repeat this process to update these settings at any time.

During the setup, the instrument provides guidance through voice prompts and blinking indicators on the display screen for each parameter. Users can navigate options using the left and right selection buttons and confirm their choice by briefly pressing the mode button. The instrument saves the selected settings and automatically moves to the next parameter until the setup is complete.

5. Special Remarks

5.1Analyzer

The analyzer is a precision instrument, and prolonged use may lead to dust and debris accumulation, potentially affecting its performance. To ensure reliable operation, regular maintenance is essential. Please observe the following guidelines during use:

- The instrument's service life is 5 years.
- Avoid cleaning the test strip slot.

●Do not pour liquids into the test strip slot or onto the buttons.

●Never immerse the instrument in liquid.

●Store the instrument in its case after each use.

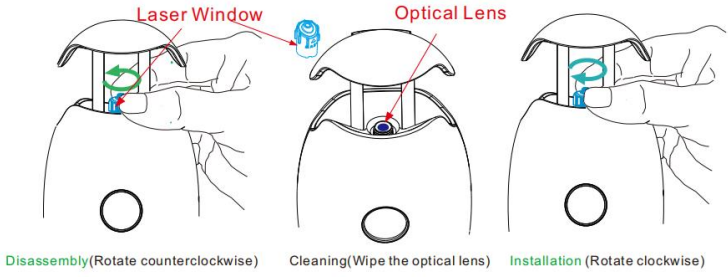
●Maintain storage temperatures between -10°C and 55°C, with room temperature being ideal.

●If unused for an extended period, recharge the instrument at least once every 3 months to prevent battery damage.

●The optical lens inside the instrument is a precision component. To ensure optimal blood collection performance, clean the lens daily before use. Perform cleaning in an environment free of dust, lint, or other debris. Please follow these steps:

a） Turn off the instrument, pull out the lever, and rotate the laser window counterclockwise to remove it. Set it aside carefully；

b）Adjust the instrument's angle for better access to the lens. Use an alcohol wipe or a cotton swab lightly moistened with alcohol to clean the lens, wiping repeatedly in one direction. Allow the lens to air dry completely, or wipe it again with a dry cotton swab or lens cloth. Avoid touching the lens after cleaning；



c）Reattach the laser window by rotating it clockwise until the "▲" symbol is at the top and the window is securely in place. Push the lever back in。

The laser window is a replaceable component. If the original laser window is damaged or lost during use or maintenance, contact the manufacturer to purchase a replacement. Install the new window following the instructions provided above.

When cleaning the optical lens, ensure the instrument is powered off to prevent accidental activation that could damage the lens or cause eye injury.

Note: Avoid performing blood sampling without the laser window installed, as this could result in sampling failure or damage to the instrument.

5.2 Test Strip

Refer to the test strip user manual for detailed instructions. After removing a test strip from the container, close the lid immediately to prevent the remaining strips from becoming damp and unusable.

6. Information and Troubleshooting

Improper operation may cause unsuccessful blood sampling or inaccurate results. If issues arise, consult the troubleshooting table for guidance.

Issue	Possible Causes	Usage Suggestions
The blood collection function is not	The lever is not properly engaged	Pull the lever to the correct position until you hear a faint "click" or feel a slight resistance

working properly	Low battery power	Charge the instrument immediately
When triggered, the finger either does not bleed or produces an insufficient amount of blood	Blood collection setting is too low	Adjust the blood collection setting to a higher level
	Unsuitable blood collection site on the fingertip, thick fingertip skin, or poor blood circulation	Select a soft, callus-free area, such as the side of the finger. Massage or apply a warm compress to the finger to increase temperature and improve blood flow before collecting blood
	Alcohol residue remains at the blood collection site	Ensure the alcohol has fully evaporated before proceeding with blood collection
	The optical lens is contaminated	Remove the laser window and clean the instrument's optical lens. Refer to Section 5.1 for detailed instructions
	The finger moves, shakes, or retracts during the blood collection process	Light and sound emissions during blood collection are normal. Keep the designated blood collection area of your finger firmly pressed against the laser window surface until you hear the voice prompt "Please add the blood sample to the test strip". Then, proceed with blood collection
Suspected irregular blood glucose test results or failure to measure blood glucose after sample collection	Non-approved test strips were used, or the test strips have expired	Use test strips specified by the manufacturer, or replace them with new test strips that are within the valid (opened) usage period
	The test strip was improperly inserted into the instrument, or there was a prolonged delay	Replace expired test strips with new ones within the valid (opened) usage period. When correctly inserted, the instrument will emit a "beep" sound

	before sample application	
	The blood sample was insufficient or applied inconsistently	After blood collection, repeatedly press and release the finger to enhance blood flow. Position the test strip at an angle of 0° to 40° relative to the finger to facilitate quick and successful blood collection
Noticeable pain or excessive bleeding	The blood collection setting is too high	Lower the blood collection setting as needed

If the issue persists, please contact our customer service team at 400-895-8318, your local distributor, or consult a medical professional.

Important Notes: During the blood collection process, the instrument may emit a faint clicking sound and light, accompanied by a small amount of smoke-like vapor at the collection site. This is a normal phenomenon and does not affect the instrument's functionality.

If an error occurs, the instrument malfunctions, or an unexpected situation arises, the display will show corresponding prompt messages. Refer to the table below for details.

Information	Meaning	Usage Recommendation
HI	The measurement exceeds the upper limit of the specified range	Retest to confirm whether the measurement still exceeds the upper limit, and consult a healthcare professional for further diagnosis and advice

LO	The measurement is below the lower limit of the specified range	Retest to confirm whether the measurement still falls below the lower limit, and consult a healthcare professional for further diagnosis and advice
E01	Test strip error: The strip is expired, previously used, or incompatible with the analyzer	Use a manufacturer-approved test strip within its (opened) valid period to retest
E04	Sample error: Insufficient sample or incorrect sample type	Use a manufacturer-approved test strip within its (opened) valid period to retest. Only human blood or the compatible control solution should be used for testing
E06	Hardware malfunction in the detection module	Restart the instrument. If the issue persists, contact your local distributor or the after-sales service team
E10	Test timed out	Use a manufacturer-approved test strip within its (opened) valid period to retest. If the issue persists, contact your local distributor or the after-sales service team
E31	Laser blood collection preparation timed out	Restart the instrument. If the issue persists, contact your local distributor or the after-sales service team
E33	Battery power is low	If this message appears, the laser blood collection function will be disabled, but other measurement operations can still be performed. To restore full functionality, connect the instrument to a charger promptly
E40	Battery critically low	Connect the instrument to a charger promptly. If the issue persists, contact your local distributor or the after-sales service team

7. Technical Specifications

Detection Technology		Electrochemical Biosensing Technology	
Intended Use		Detection of glucose, 3-Hydroxybutyric acid, and uric acid concentrations in adult capillary whole blood.	
Operating Temperature Range		5℃ to 40℃ (optimal range: 15℃ to 35℃)	
Operating Humidity Range		≤80% RH	
Storage Temperature Range		-10℃ to 55℃	
Storage Humidity Range		≤93% RH	
Plasma glucose, 3-Hydroxybutyric acid, uric acid concentrations		Plasma glucose, 3-Hydroxybutyric acid, uric acid concentrations	
Altitude Limit		0m to 3000m	
Blood Glucose	5s±1s	Blood Glucose	5s±1s
3-Hydroxybutyric acid	9s±1s	3-Hydroxybutyric acid	9s±1s
Uric Acid	15s±1s	Uric Acid	15s±1s
Blood Glucose	0.6mmol/L-33.3mmol/L	Blood Glucose	0.6mmol/L-33.3mmol/L
3-Hydroxybutyric acid	0.1mmol/L-8.0 mmol/L	3-Hydroxybutyric acid	0.1mmol/L-8.0 mmol/L
Uric Acid	179 μmol/L-1190 μ mol/L	Uric Acid	179 μmol/L-1190 μ mol/L

This instrument utilizes a solid-state laser to emit a laser beam, which is shaped and precisely focused on the blood sampling site for efficient blood collection.	This instrument utilizes a solid-state laser to emit a laser beam, which is shaped and precisely focused on the blood sampling site for efficient blood collection.	
Accuracy	Blood Glucose	For values ≤4.2 mmol/L, the allowable deviation should not exceed ±0.83 mmol/L; For values >4.2 mmol/L, the allowable deviation should not exceed ±20%.
	3-Hydroxybutyric acid	For values <1.5 mmol/L, the allowable deviation should not exceed ±0.15 mmol/L; For values ≥1.5 mmol/L, the allowable deviation should not exceed ±15%.
	Uric Acid	For values <400 μmol/L, the allowable deviation should not exceed ±80 μmol/L; For values ≥400 μmol/L, the allowable deviation should not exceed ±20%.
Repeatability	Blood Glucose	For values <5.5 mmol/L, the SD should be <0.42 mmol/L; For values ≥5.5 mmol/L, the CV should be <7.5%.
	3-Hydroxybutyric acid	For values <1.5 mmol/L, the SD should be <0.075 mmol/L; For values ≥1.5 mmol/L, the CV should be <5%.

	Uric Acid	For values <400 μmol/L, the SD should be ≤40 μmol/L; For values ≥400 μmol/L, the CV should be ≤10%.
Measurement Units	Blood Glucose	mmol/L or mg/dL
	3-Hydroxybutyric acid	mmol/L
	Uric Acid	μmol/L
Data Storage Capacity	≤10,000 sets	
Laser Output Mode	Single Pulse	
Single-Pulse Laser Energy	40-170mJ	
Single-Pulse Laser Width	40 μs-750 μs	
Drill Hole Diameter	≤1.2mm	
Laser Medium	Erbium-doped Yttrium Aluminum Garnet (Er:YAG)	
Battery Specifications	3.7V Lithium Battery	
Power Adapter (Optional)	Input: 100-240V-50/60Hz, 50VA; Output: 5.0V, 1.0A	
Dimensions	80 × 135 × 36 mm (Width × Length × Thickness)	
Weight	≤240g	
Recovery Time after High/Low-Temperature Storage	45min	
Internal Battery Lifespan	5 years	

8. Special Instructions

8.1 Instructions for Use

8.1.1 Physiological Conditions That May Affect Results

>Hematocrit (HCT) levels outside the valid range of the test strips.

>Impaired peripheral blood circulation or reduced blood volume caused by conditions such as severe dehydration, low blood pressure, shock, or peripheral vascular disease.

8.1.2Improper Operations That May Affect Measurement Accuracy or Laser Blood Collection Efficiency

>Insufficient blood volume, failing to completely fill the reaction area of the test strip.

>Adding more blood to the same test strip after an initial insufficient sample.

>Using abnormal blood samples, such as those with air bubbles or excessive interstitial fluid.

>Reusing a test strip after applying blood.

>Using test strips that are expired or improperly stored.

>Disinfecting with iodine tincture or chlorine-based solutions.

>Collecting blood before the alcohol used for disinfection has fully evaporated.

>Leaving the test strip exposed to high temperatures for more than 3 minutes after removal from the container.

>Not calibrating the instrument with the code card from the test strip box when using a new uric acid test strip package.

>Failing to allow the instrument to stabilize to the operating environment's temperature (typically requires at least 20 minutes).

8.2Safety and Maintenance

During transportation, the packaged instrument should be protected from heavy impacts, vibrations, moisture, and direct sunlight.

Do not expose the instrument to impacts, water, or conditions outside the specified temperature and humidity ranges in the manual. Avoid looking directly into the light output.

The optical lens inside the instrument is a precision component. To ensure optimal blood collection performance, clean the lens daily before use (refer to Section 5.1 for detailed cleaning instructions). Use an alcohol wipe or a lint-free cotton swab moistened with a small amount of alcohol to clean it thoroughly. Allow the lens to fully air dry before using the instrument.

If any operational issues or malfunctions occur during use, please contact the company's after-sales service department.

Refer to the test strip manual for proper storage instructions.

8.3Network Security Guidelines

8.3.1 Electronic Interface

The analyzer's electronic interface is a network port used to access blood

glucose, 3-Hydroxybutyric acid, and uric acid test data. This data is non-sensitive medical information and does not contain any personal information. Key features include:

>Network Type: Bluetooth, Wi-Fi;

>Network Categories: Personal Area Network (PAN), Local Area Network (LAN);

>Interface Type: Electrical port;

>Data Interface: Proprietary communication protocol;

>Remote Access and Control: Not supported;

>Performance Specifications: Wi-Fi and Bluetooth data transmission baud rate: 115,200.

8.3.2 User Access Control

8.3.2.1User Authentication Method: Custom instrument-specific format verification.

8.3.2.2User Types and Permissions:

User Type: Standard User.

User Permissions: Transmit instrument test results.

8.3.3 Network Security Features Configuration

The instrument ensures network security capabilities, including authenticity, integrity, and confidentiality of data transmission. These features are pre-configured by the manufacturer and cannot be modified by the operator.

8.3.4 Usage Restrictions

1）To access measurement data from the instrument via the smart terminal software, the instrument must first be paired with the software using Bluetooth. Each instrument can only be linked to a single account. Other accounts cannot pair with the instrument or access its data.

2）The instrument supports data access through wireless networks such as WiFi or Bluetooth, but only one type of connection can be active at any given time.

8.4Precautions：

This instrument is an in vitro diagnostic medical instrument designed for self-testing. Users must thoroughly read the accompanying user manual before use and strictly adhere to the instructions to prevent compromising the instrument's protective features, which could lead to harmful radiation exposure.

>Do not modify this instrument under any circumstances.

>Warning: Improper use of electrical equipment may result in fatal electric shock, burns, fire, or other hazards. Always follow the instructions in the product manual.

>Use the instrument solely for the purposes specified in the manual.

>Ensure the instrument is operated in an environment with a temperature range of 5°C to 40°C.

>Use only manufacturer-specified test strips; do not use other types.

>When healthcare professionals or others assist a patient with testing, appropriate protective gear must be worn.

>Avoid forcefully pulling the laser window lever during operation to prevent unnecessary damage to the instrument.

>When not in use, return the lever to its original position and store the instrument in a suitable environment.

>The laser glucose meter contains high-voltage components. To avoid electric shock, do not attempt to disassemble the instrument.

>Do not point the laser window at any part of the body other than the finger, especially sensitive areas such as the eyes, to avoid injury.

>During operation, the laser window emits Class 4 laser radiation. Avoid direct or scattered radiation exposure to the eyes or skin.

>Do not use the instrument in the presence of flammable anesthetics or oxidizing gases (e.g., nitrous oxide [N_2O] or oxygen). Materials such as cotton may ignite when exposed to high temperatures from normal laser operation in oxygen-rich environments.

>In dry environments, especially those with synthetic materials (e.g., carpets), the instrument may be susceptible to damaging electrostatic discharge. Handle with care to prevent harm.

>Avoid operating the instrument near radiation sources, as this may interfere with its normal function.

>Solvents and flammable solutions used for cleaning and disinfection must fully evaporate before using the laser instrument to prevent ignition of internal gases.

>Do not immerse the instrument in liquid or place it in locations where it could fall into liquid.

>Never charge the instrument if it is wet or has been exposed to moisture.

>Never leave the instrument unattended while it is plugged into a power source.

>Avoid using the instrument if it is malfunctioning or damaged.

Important Notes： Examples of typical defects include:

a）Damage to the charging cable or its plug.

b） Damage caused by dropping the instrument.

c) Damage resulting from submersion in water or water spillage on the instrument.

★Do not place the instrument or its charging cable on surfaces exposed to fire or excessive heat.

★Unplug the charger immediately after charging is complete before using the instrument.

★Avoid placing any objects on top of the instrument.

★Unless explicitly stated in the user manual, do not insert or drop any items into the instrument's openings or seams.

★Do not operate the instrument in areas with aerosol sprays or oxygen-enriched environments.

★The instrument is not designed for outdoor use.

★Ensure the instrument is positioned where its disconnection mechanism can be easily accessed.

★When used by or near individuals with disabilities or patients, appropriate supervision is required.

★During use, the laser window surface that comes into contact with skin (hereinafter referred to as the "laser window surface") may become contaminated with blood or other substances. Clean it thoroughly after each use.

★Repairs must be performed only by the manufacturer. Do not attempt to disassemble or repair the instrument yourself.

★If the instrument requires factory repair, disinfect it with alcohol before shipping it back.

★Do not disassemble or dispose of the instrument when it reaches the end of its service life. Dispose of it according to local regulations.

★Used test strips and alcohol pads should be placed in a biohazard waste container for proper disposal.

★The instrument's battery should only be replaced by the manufacturer. Do not attempt to replace it yourself, as improper disassembly may result in fire or explosion hazards.

★Strong light can affect the instrument's display. Avoid using it in direct bright light.

★Avoid using the instrument in environments with high noise or vibration, as this can interfere with voice prompts or testing functions.

★Do not use the instrument in dusty environments, as dust may affect blood sampling accuracy.

★Keep the instrument out of reach of pets, insects, or children to prevent damage or other unwanted harm.

★The charging port is only compatible with USB Type-C cables; other types of charging cables are not supported.

Key Features:

a） The instrument allows users to adjust the blood sampling settings. It should charge appropriately based on the selected setting and trigger correctly once charging is complete.

b) The analyzer is capable of testing samples for glucose, 3-Hydroxybutyric acid, or uric acid. Upon completing the test, it should display and store the results efficiently.

9. Scope of Application and Contraindications

9.1Scope of Application

The "Jinmangguo I," "Jinmangguo II," and "Jinmangguo III" series Blood Glucose, Blood Ketone and Uric Acid Analyzers are designed for use with their

corresponding test strips: glucose test strips (using glucose oxidase or glucose dehydrogenase methods), 3-Hydroxybutyric acid test strips (electrochemical method), and uric acid test strips (electrochemical method). These instruments perform quantitative testing of glucose, 3-Hydroxybutyric acid, and uric acid concentrations in capillary whole blood samples from adult fingertips. The analyzers can be operated by clinical healthcare professionals or trained non-professionals. They are intended exclusively for monitoring blood glucose, 3-Hydroxybutyric acid, and uric acid levels in adults. These instruments are not suitable for diagnosing or screening diseases such as diabetes or gout and should not be used as a basis for adjusting treatment medications.

9.2Contraindications

★Conditions such as dehydration, edema, anemia, or dialysis that result in HCT levels outside the range suitable for the compatible test strips.

★Users who are blind or have severe visual impairment and cannot operate the instrument independently.

★Individuals taking unidentified medications.

10. Electromagnetic Compatibility

Important Notes:

★The analyzer meets the electromagnetic compatibility requirements of the YY 9706.102 standard.

★Users should follow the electromagnetic compatibility guidelines provided

in the accompanying documentation for proper installation and operation.

★Portable and mobile RF communication instruments may interfere with the analyzer's performance. To ensure accurate operation, avoid strong electromagnetic interference, such as proximity to microwave ovens.

★For detailed guidelines and the manufacturer's declaration, refer to the appendix.

Warning:

★The analyzer should not be placed near or stacked with other instruments. If such placement is unavoidable, ensure proper testing and validation to confirm normal operation in the intended configuration.

★Using accessories or cables not specified by the manufacturer or those not provided as spare parts for internal components may increase emissions or reduce the instrument's immunity to interference.

★Wireless transmission and reception specifications: Reception frequency: 2.4 GHz; Transmission frequency: 2.4 GHz; Radiated power: 15 dBm.

★ Symbol for non-ionizing radiation: 

★ Even if other instruments meet national emission standards, the analyzer may still be susceptible to interference from them.

No.	Cable Name	Cable Length	Shielded (Yes/No)
1	USB Connection Cable	0.8 m	No

Appendix:

<table>
<tr><th colspan="3">Guidelines and Manufacturer's Declaration – Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The analyzer is designed for use in the specified electromagnetic environment. Users or purchasers must ensure that it operates within these conditions:</td></tr>
<tr><td>Emission Tests</td><td>Conformity</td><td>Electromagnetic Environment – Guidelines</td></tr>
<tr><td>RF Emissions
GB 4824</td><td>Group 1</td><td rowspan="2">The analyzer utilizes RF energy exclusively for internal functions, resulting in minimal RF emissions with a low likelihood of interfering with nearby electronic instruments.</td></tr>
<tr><td>RF Emissions
GB 4824</td><td>Class B</td></tr>
<tr><td>Harmonic Emissions
GB 17625.1</td><td>Class A</td><td rowspan="2">It is suitable for use in all environments, including residential settings and facilities connected directly to public low-voltage power supply networks in residential buildings</td></tr>
<tr><td>Voltage Fluctuations/Flicker Emissions
GB 17625.2</td><td>Compliant</td></tr>
</table>

Guidelines and Manufacturer's Declaration – Electromagnetic Immunity			
The analyzer is designed for use in the specified electromagnetic environment. The purchaser or user must ensure its operation within such an environment:			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic Discharge: GB/T 17626.2	±6 kV for contact discharge ±8 kV for air discharge	±6 kV for contact discharge ±8 kV for air discharge	Flooring should be made of wood, concrete, or ceramic tiles. If synthetic materials are used, the relative humidity must be at least 30%.
Electrical Fast Transient/Burst: GB/T 17626.4	±2 kV for power lines	±2 kV for power lines	The mains power supply should meet the standard quality typically required in commercial or hospital environments.
Surge Protection: GB/T 17626.5	±1 kV line-to-line ±2 kV line-to-ground	±1 kV line-to-line	The mains power supply should meet the standard quality typically required in commercial or hospital environments.

Voltage Dips, Short Interruptions, and Fluctuations in Power Input GB/T 17626.11	<5% UT, lasting 0.5 cycles (>95% voltage dip based on UT) 40% UT, lasting 5 cycles (60% voltage dip based on UT) 70% UT, lasting 25 cycles (30% voltage dip based on UT) <5% UT, lasting 5 seconds (>95% voltage dip based on UT)	<5% UT, lasting 0.5 cycles (>95% voltage dip based on UT) 40% UT, lasting 5 cycles (60% voltage dip based on UT) 70% UT, lasting 25 cycles (30% voltage dip based on UT) <5% UT, lasting 5 seconds (>95% voltage dip based on UT)	The mains power supply should meet the typical quality standards of commercial or hospital environments. For uninterrupted operation of the laser glucose meter during power outages, the use of an uninterruptible power supply or battery is recommended.
Power Frequency Magnetic Fields (50/60Hz) GB/T 17626.8	3A/m	3A/m	The power frequency magnetic field should align with the typical levels found in commercial or hospital environments.
Note: UT refers to the AC mains voltage applied before the test voltage			

Guidelines and Manufacturer's Declaration – Electromagnetic Immunity			
The analyzer is designed for use in the specified electromagnetic environment. The purchaser or user must ensure its operation within such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance**	**Electromagnetic Environment – Guidance**
RF Conducted Disturbance: GB/T 17626.6 RF Radiated Disturbance: GB/T 17626.3	3 V (RMS) 150 kHz -80 MHz 3 V/m 80 MHz - 2.5 GHz	3 V 3 V/m	Communication Equipment Portable and mobile RF communication instruments, including cables, must not be used closer to the laser glucose meter than the recommended separation distance. The separation distance should be determined using a formula corresponding to the $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz～800 MHz $d = 2.3\sqrt{P}$ 800 MHz～2.5 GHz Where: P: The transmitter's maximum rated output power (in watts, W), as specified by the manufacturer. d: The recommended separation distance (in meters, m)b. The field strength of fixed RF transmitters should be assessed through an

			electromagnetic site surveyc. For each frequency ranged, the measured field strength should remain below the specified compliance level.  ay occur in the ipment marked ing symbol.

Note 1: For frequencies of 80 MHz and 800 MHz, the higher frequency formula should be used.

Note 2: These guidelines may not apply in all situations, as electromagnetic propagation can be influenced by absorption and reflection from buildings, objects, and people.

a.Fixed transmitters, such as base stations for wireless (cellular/cordless) phones, land mobile radios, amateur radios, AM/FM radio broadcasts, and television broadcasts, may generate unpredictable field strengths. To evaluate the electromagnetic environment of fixed RF transmitters, site surveys should be conducted.If the measured field strength at the analyzer's location exceeds the specified RF compliance level, the instrument should be monitored to confirm normal operation.If abnormal performance is observed, additional actions, such as repositioning or reorienting the instrument, may be necessary.

b. Across the 150 kHz to 80 MHz frequency range, the field strength should not exceed 3 V/m.

Recommended Separation Distance between Portable/Mobile RF Communication Equipment and the Analyzer

The analyzer is designed for use in controlled electromagnetic environments where RF radiated disturbances are managed. To minimize electromagnetic interference, users or purchasers should maintain the recommended minimum separation distance between portable or mobile RF communication instruments (transmitters) and the analyzer, based on the maximum rated output power of the communication equipment.

Maximum Rated Output Power of Transmitters Power (W)	**Separation Distances (m) for Different Transmitter Frequencies**		
	150 kHz - 80 MHz $d = 1.2\sqrt{P}$	**80 MHz - 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz - 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with a maximum rated output power not listed in the table, the recommended separation distance, d (in meters, m), can be calculated using the formula provided in the corresponding frequency range column. Here, P represents the transmitter's maximum rated output power, specified by the manufacturer, in watts (W).

Note 1: At frequencies of 80 MHz and 800 MHz, the formula for the higher frequency range should be applied.

Note 2: These guidelines may not be applicable in all situations, as electromagnetic propagation is affected by absorption and reflection from buildings, objects, and people.

11. After-Sales Service Information

【Basic Information】

Registrant/Manufacturer: Shenzhen Beifu Biomedical Technology Co., Ltd.

Registered Address: 2-G,2nd Floor,Building 4,(No.28, Lanshan Road), Tongchan New Materials Industrial Park, No.28, Songpingshan Community,Xili Street, Nanshan District,Shenzhen

Production Address: 2-A-02,2nd Floor,Building 4,(No.28, Lanshan Road), Tongchan New Materials Industrial Park, No.28, Songpingshan Community,Xili Street, Nanshan District,Shenzhen

After-Sales Service Provider: Shenzhen Beifu Biomedical Technology Co., Ltd.

Contact Number: 400-895-8318

Production License Number: Y.S.Y.J.X.S.C.X. No. 20224690

Medical Instrument Registration Certificate Number/Instrument Technical Requirements Number: Y.X.Z.Z. No. 20232221618

Manual Preparation Date: June 30, 2022

Basic Information on Compatible Test Strips:

1、Blood Glucose Test Strips (Glucose Oxidase Method):

Model/Specifications: VGS01, available in packaging options of 10, 25, 50, 100, or 200 tests per box.

Registrant: Hangzhou VivaChek Biotechnology Co., Ltd.

Address: 2nd Floor, Building 2, No. 146 Chaofeng East Road, Yuhang Economic and Technological Development Zone, Hangzhou, Zhejiang Province

Production License Number: Z.Y.J.X.S.C.X. No. 20140148

Medical Instrument Registration Certificate/Product Technical Requirements Number: Z.X.Z.Z. No. 20152401002

2、Blood Glucose Test Strips (Glucose Dehydrogenase Method):

Model/Specification: VGS02, available in packaging options of 10, 25, 50, 100, or 200 tests per box.

Registrant: Hangzhou VivaChek Biotechnology Co., Ltd.

Address: 2nd Floor, Building 2, No. 146 Chaofeng East Road, Yuhang Economic and Technological Development Zone, Hangzhou, Zhejiang Province

Production License Number: Z.Y.J.X.S.C.X. No. 20140148

Medical Instrument Registration Certificate/Product Technical Requirements Number: Z.X.Z.Z. No. 20182400128

3、3-Hydroxybutyric acid Test Strips (Electrochemical Method):

Model/Specification: VKS01, available in packaging options of 1, 10, 25, 50, 75, 100, or 200 tests per box.

Registrant: Hangzhou VivaChek Biotechnology Co., Ltd.

Address: 2nd Floor, Building 2, No. 146 Chaofeng East Road, Yuhang Economic and Technological Development Zone, Hangzhou, Zhejiang Province

Production License Number: Z.Y.J.X.S.C.X. No. 20140148

Medical Instrument Registration Certificate/Product Technical Requirements Number: Z.X.Z.Z. No. 20212400530

4、Uric Acid Test Strips (Electrochemical Method):

Model/Specification: VUS01, available in packaging options of 1, 10, 25, 50, 75, 100, or 200 tests per box.

Registrant: Hangzhou VivaChek Biotechnology Co., Ltd.

Address: 2nd Floor, Building 2, No. 146 Chaofeng East Road, Yuhang Economic and Technological Development Zone, Hangzhou, Zhejiang Province

Production License Number: Z.Y.J.X.S.C.X. No. 20140148

Medical Instrument Registration Certificate/Product Technical Requirements Number: Z.X.Z.Z. No. 20212400558

Warranty Card

(Please Retain Carefully)

Product Model: _____

Purchase Date: _____

Customer Name: _____

Contact Number: _____

Product Serial Number: _____

Shipping Address: _____

Friendly Reminder:

★If you have any questions during use, please contact our customer service hotline at 86+400-895-8318.

★The product is covered by a one-year warranty from the date of purchase, provided it is used normally and has not been disassembled.

★For repair services, please complete the warranty card accurately and send it along with the instrument to us.

Thank you for choosing our product!

A smart health companion dedicated to supporting

SHENZHEN BEIFU BIOMEDICAL TECHNOLOGY CO . ,LTD