eBuricacid eB-U01

Blood Uric Acid Monitoring System

User's Manual

VISGENEER INC.
No. 335, Sec. 6, Zhonghua Rd.,
30094 Hsinchu City, Taiwan

Tel : 886-3-5181918
Fax : 886-3-5181908
E-mail :
eB@visgeneer.com
Website :
www.eB-monitor.com
www.visgeneer.com

CE 0123

Ver.3
1320573

eB monitor
easy Blood monitoring

Welcome

Thank you for selecting the eBuricacid Blood Uric Acid Monitoring System. This manual provides all the information you need to get accurate test results. Please read this entire manual carefully before you proceed with testing.

At Visgeneer, we believe in the value of early prevention over later treatment. eBuricacid Blood Uric Acid Monitoring System is developed under this vision and is manufactured and supported by us. For any questions or concerns, please feel free to reach out to us or our local agent. Our contact information is located in the back cover of this manual.

Intended Use

The eBuricacid Blood Uric Acid Monitoring System is intended for the quantitative measurement of uric acid in fresh capillary whole blood. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (Over-the-counter [OTC]) by person with hyperuricemia, or in clinical setting by health care professionals, as an aid to monitor the effectiveness of hyperuricemia. The test results are plasma equivalent. The measuring range of uric acid concentration in capillary whole blood is from 3 to 20 mg/dL (179-1190 μmol/L).

Test Principle

The technology used for the eBuricacid Blood Uric Acid Monitoring System is based on the principle that small electrical currents are produced when blood uric acid reacts with the reagent immobilized on the reaction area of the eBuricacid test strip and the current change is proportional to the amount of uric acid in the blood.

Calibration Reference

The eBuricacid Blood Uric Acid Monitoring System is calibrated plasma equivalent results, which is traceable to a NIST standard SRM 913b. The plasma was used for calibration and using the LANNER Uric acid reagent kit by HITACHI 704 automatic analyzer.

Table of Contents

1. eBuricacid Blood Uric Acid Monitoring System

1.1 The eBuricacid System

The eBuricacid Blood Uric Acid Monitoring System is intended to monitor blood uricacid level in fresh capillary whole blood. The system is for in vitro diagnostic use only and should be used outside the body. Also, please do the test only with eBuricacid test strips.

1.2 Equipment in Package

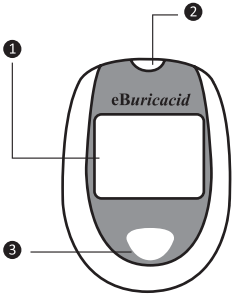
Please check the kit package for the eBuricacid Blood Uric Acid Monitoring System which includes the following items. If not, please contact our local agent or return to the purchased store.

Items Included	Optional Items
1. Meter Device	1. Blood Uric Acid Test Strips
2. User's Manual	2. Code Card
3. Lancing Device	3. Lancets
4. Warranty Card	4. One 3-volt Lithium Battery (CR2032)
	5. Control Solution

1.3 Product Specification

eBuricacid Blood Uric Acid Monitoring System	
1. System Model	eB-U01
2. Measuring Range	3~20 mg/dL (179~1190 μmol/L)
3. Measuring Time	15 seconds
4. Measuring Unit	mg/dL or μmol/L (Interchangeable)
5. Blood Sample Type	Capillary whole blood
6. Acceptable Hematocrit Range	30-60 %
7. Blood Volume	0.5 μL
8. Memory Capacity	180 results with time and date
9. Time Display	24 H
10. Operating Temperature Range	10~40 °C
11. Relative Humidity Operating Range	Below 85%
12. Test Strip Storage Temperature	4-30 °C
13. Meter Storage Condition	0-50 °C
14. Meter Storage Humidity Range	Below 95%
15. Power Supply	One 3-volt lithium battery (CR2032)
16. Dimension L×W×H (mm)	86x63x15 mm
17. Weight	≦50 g

2. About eBuricacid Blood Uric Acid Monitoring System

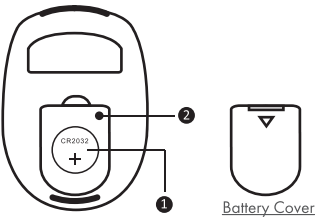


The front side of the test meter

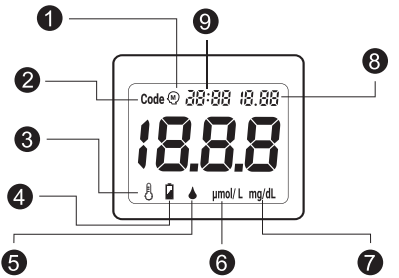
1. Screen: Show test result, information and past results stored in memory.
2. Test slot: Insert test strip and code card.
3. Button: Use to recall memory or adjust values in setting mode.

The back side of the test meter

1. Battery slots: Put in one 3-volt lithium battery (CR2032).
2. Setting knob: Press to set up year, time, date and measurement unit.

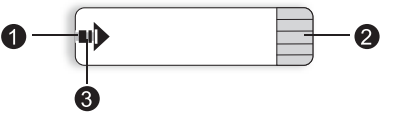


Screen description



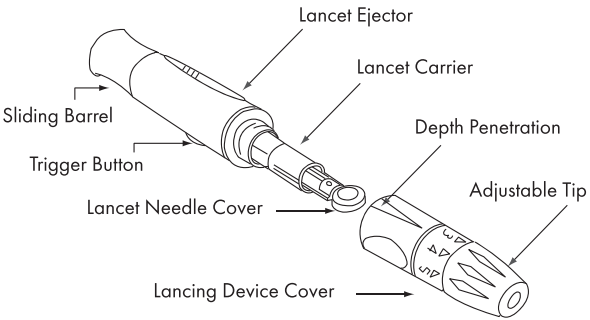
❶ Memory sign
❷ Code sign
❸ Thermograph
❹ Battery sign
❺ Blood drop sign
❻ Measuring unit: μmol/L
❼ Measuring unit: mg/dL
❽ Date
❾ Time

Test strip

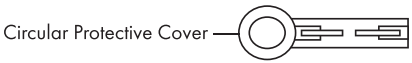


❶ Top edge: Apply blood sample to here.
❷ Meter connect edge: Insert this side to meter.
❸ Indication slot: To make sure if blood has been applied enough to fill the reaction area.

Lancing set



Lancing Device



Lancet

3. Operating Procedure

3.1 Before Testing

3.1.1 Installing the Battery

eBuricacid testing meter requires one 3-volt lithium battery (CR2032).

Step 1 Open the battery cover.

Step 2 Put one 3-volt lithium battery (CR2032).

Step 3 After you put in the battery properly, you'll hear a "beep" sound.

Step 4 Follow section 3.1.2 to set up time and date.

Step 5 Place the battery cover back.

When the battery power is low, a battery sign will be shown on the screen. Follow the steps above to replace the battery.

Note : If you do not test frequently, please remove the battery from battery socket, in case of leaking and causing damage to the meter.

Use the correct battery for this product.

3.1.2 Setting Mode

Setting mode is triggered when installing battery for the first time, changing the battery or pressing the Setting knob to set up time and date.

Step 1 Open the battery cover and find the setting knob on the top right corner above the battery slot.

Step 2 Press and release the setting knob, the year digits start flashing on the screen.

Step 3 Press and release the button on the front side of the meter to adjust the digits until the correct year is shown on the screen. (Only last two digits of year are shown on the screen, for example: 2021).

Step 4 Press and release the setting knob, the month digits start flashing on the screen.

Step 5 Press and release the ◡ button on the front side of the meter to adjust the digits until the correct month is shown on the screen.

Step 6 Press and release the setting knob, the day digits start flashing on the screen.

Step 7 Press and release the ◡ button on the front side of the meter to adjust the digits until the correct day is shown on the screen.

Step 8 Press and release the setting knob, the hour digits start flashing on the screen.

Step 9 Press and release the ◡ button on the front side of the meter to adjust the digits until the correct hour is shown on the screen.

Step 10 Press and release the setting knob, the minute digits start flashing on the screen.

Step 11 Press and release the ◡ button on the front side of the meter to adjust the digits until the correct minute is shown on the screen.

Step 12 Press and release the "setting" knob to set the measurement unit.

Step 13 Press and release the ◡ button on the front side of the meter for 3 seconds to switch the measurement unit between mg/dL and μmol/L.

Step 14 Press and release the setting knob, "OFF" will appear on the screen to exit the setting mode.

You may skip Step 3.1.3 of the instruction, when new vial of strips uses the same code that was previously set on the meter.

3.1.3 Coding the Meter

For accurate results, your meter should be calibrated with the code card every time when you open a new vial of test strips. After calibrating the meter with a code card, it's time to start testing.

Step 1. Open a new box of test strips and take out code card from the box.
Step 2. Insert the code card into the test slot.
Step 3. You will hear a "beep" sound and a code number appears on the screen.
Step 4. Check the code number on the screen with the number on the vial of test strips. These two numbers should match. If not, please stop testing and contact our local agent.
Step 5. Remove the code card and you are ready for testing.

Note:
* Insert the code card or strip into the test slot. "CH-" will be shown on the screen and the meter will self-detect. If self-detection fails, "E01" will appear on the screen. If the meter is functioning properly, the code of the code card will be shown on the screen.

3.2 Start Testing

Step 1. Remove the cap from the lancing device.
Step 2. Insert a lancet into the lancing holder and push it down until it is fully seated.

Step 3. Twist the circular protective cover in the front of the lancet. Then, remove the protective cover from the lancet.
Step 4. Put the cap back onto the lancing device.
Step 5. You have to adjust the depth setting of lancing device before using. There are 5 levels of depth you can choose. Level 1 is the shallowest one. Level 5 is the deepest one.
Step 6. Choose a desired skin penetration depth for yourself by rotating the depth selector until the depth selection window displays your desired depth setting.
Step 7. Slide the ejection/cocking control back until it is triggered.
Step 8. Wash your hands with warm, soapy water. Rinse and dry thoroughly.
Step 9. Open a new vial of test strips. Take out a test strip from the vial and close the cap properly.
Step 10. Follow the arrow direction to insert the test strip into test slot. The meter will turn on automatically when you insert the test strip properly.
Step 11. Then, the code number will be shown on the screen with a "beep" sound. Please confirm if this code is the same as the code on the vial label.
Step 12. Put your hands on a table and press the lancing device against your fingertip.
Step 13. Push the trigger on the lancing device and the lancet will prick your finger.
Step 14. To obtain a drop of blood, squeeze your finger gently to form a small drop of blood.
Step 15. Then, confirm the blood drop sign is flashing on the screen before you apply the blood sample to the strip.
Step 16. The blood will be drawn into the strip automatically. You can confirm the blood is enough or not by observing the indication slot. If the blood is not enough to fulfill the reaction well, do not add more blood to the strip and discard the strip. Please repeat the test again.

Step 17. Hold your blood to the strip until after you hear the "beep" sound.
Step 18. The meter will begin to count down from 15 seconds.
Step 19. After counting down from 15 to 1, your test result will appear on the screen and be stored automatically in the meter's memory.
Step 20. Remove the test strip and the meter will turn off automatically.
Step 21. Dispose the used strip in a sealed container.
Step 22. Remove the cap from the lancing device and put the protective cover back onto the lancet.
Step 23. Push the ejector forward and dispose the lancet to a sealed container.

3.3 Accessing the Meter Memory

Your meter stores the 180 most recent test results with date and time in the memory. When the memory is full, the latest result is added to the memory and the oldest result is deleted from the memory.

Step 1 You may enter the memory mode by pressing the button on the front side of meter. "01" will flash followed by the latest results with time and date.
Step 2 Press the ◡ button on the front side of meter again to obtain the second record. The result will flash with "02".
Step 3 You may obtain all 180 records by pressing the button on the front side of meter.
Step 4 After the earliest result is shown, the symbol "OFF" will be shown on the screen to exit memory mode and then meter will shut down automatically.

4. Range of Expected Values

Blood uric acid monitoring requires the help of healthcare professionals in setting the expected range of your own blood uric acid values, arranging frequency of tests and discussing the meaning of your results. The normal value of blood uric acid concentration should be based on the definition of physiology and chemistry. That is, the fasting blood uric acid value of adults >7.0 mg/dL is hyperuricemia. In this case, please pay close attention to gout and other related complications.

Remember to repeat the test if the test result falls outside the expected range.

Reference:

1. Taiwan guideline for the management of gout and Hyperuricemia updated 2016.
2. 2016 updated EULAR evidence-based recommendations for the management of gout.

5. Quality Control Testing (Optional)

eB-series uric acid control solution is used to check if the monitoring system (meter working together with test strips) is functioning properly.

When to do a control solution test:

1. When you open a new vial of test strips.
2. Whenever you suspect that the meter or test strips are not working properly.
3. After dropping the meter.
4. Whenever you question your results.

Steps of Performing a Control Solution Test

Step 1. Remove a test strip from the vial and fasten the cap properly. Make sure the triangle sign is facing up and insert the meter connect edge of the test strip fully into the test slot. The meter will turn on automatically and the code number will be shown on the screen. Make sure that this number matches the code number on the vial of test strips.

Step 2. Open a bottle of control solution. The storing period of control solution is **only** for 3 months after the first opening or up to the expiry date, whichever comes first. **(Note: Always write down the opening date on the bottle)**.

Step 3. Hold the bottle and gently squeeze the bottle to form a small drop of control solution on the tip of the bottle. **(Note: Always shake the bottle well, discard the first drop before applying the control solution)**.

Step 4. Touch the drop of control solution to the semicircle-shaped cutout on the top of the narrow channel of the test strip. The control solution will be drawn into the strip automatically. The meter will begin to count down from 15 seconds.

Step 5. After counting down from 15 to 1, your test result will appear on the screen.

Step 6. Compare the result with the range printed on the vial of the test strips. The result should be within the range.

Control solution and test strips are necessary but may not be provided and must be purchased separately. For more information on the control solution and where to purchase them, please contact our local agent.

6. Limitation

The system will give accurate results when the following limitations are served :

◎ The test strips should not be used for the testing of neonate.
◎ The test strips are for single use only. DO NOT reuse.

◎ Handle the meter with care. **DO NOT** drop the meter on purpose or apply a strong force to the meter.
◎ **DO NOT** try to disassemble the meter.
◎ **DO NOT** use code cards from other test systems.
◎ **DO NOT** process the test with the meter placed on the hot or cold surface.
◎ Store the meter in its carrying case.
◎ Avoid getting dirt, dust, blood sample or liquid in the meter test strip port.
◎ **DO NOT** remove the test strip while the measurement is processing.
◎ **DO NOT** test with the following specimen:
1. Hematocrit range out of 30 % to 60%.
2. Plasma, serum, venous whole blood specimen.
◎ **DO NOT** perform the test if test strip is expired.
◎ Should perform the test under ambient condition, temperature 10-40 (°C) and related humidity <85%.
◎ Follow the regulations in your area to dispose the used test strips and lancing materials.
◎ Use universal blood precautions. All patient samples and materials with which they come in contact are considered biohazards and should be handled as if capable of transmitting infection.
◎ Interference: Please see the table below for the certain concentrations which can affect the function of the meter.

Substance	No Interference
Acetaminophen	<1.5 mg/dL
Ascorbic acid	<1.5 mg/dL
Bilirubin	<20 mg/dL
Cholesterol	<500 mg/dL
Dopamine	<0.09 mg/dL
L-Dopa	<1.3 mg/dL
Tolazamide	<1 mg/dL
Triglyceride	<1000 mg/dL

7. Troubleshooting

The following table is a summary of all display messages. It can help you to identify the problems. However, the message may not appear every time when the problem occurs. Improper use may cause inaccurate result without showing an error message or a symbol.

Message	Cause	Action
	The meter is abnormal.	The meter needs to be repaired. Please contact our local agent.
	The test strip is used or damp.	1. Please take a new test strip. 2. If the error message appears again, please contact our local agent.
	Insert with incorrect brand strip.	Please contact our local agent.
	When you see this sign, the battery is running low.	1. You may still use your meter and the test results will be accurate. 2. You are recommended to replace the battery at this time.
	When you see this sign with "LO", the battery must be replaced.	1. The meter is not usable and will turn off automatically. 2. Please replace with a new battery.
	The surrounding temperature is too low or high to perform a test.	Move your meter and test strips to a location where the ambient temperature is between 10°C and 40°C (50~104°F). Wait for 20 minutes then test again with a new test strip.
	Temperature is too low (below 4°C) for system to work properly. The meter will turn off automatically.	Move your meter and test strips to a location where the ambient temperature is between 10°C and 40°C (50~104°F). Wait for 20 minutes then test again with a new test strip. If the error message persists, please contact our local agent.

	Temperature is too high (above 42°C) for system to work properly. The meter will turn off automatically.	Move your meter and test strips to a location where the ambient temperature is between 10°C and 40°C (50~104°F). Wait for 20 minutes then test again with a new test strip. If the error message persists, please contact our local agent.
	Test result is higher than 20 mg/dL (1190 µmol/L).	1. Please test again with a new test strip. 2. If the error message persists, contact your healthcare professional at your earliest convenience.
	Test result is lower than 3 mg/dL (179 µmol/L).	1. Please test again with a new test strip. 2. If the error message persists, contact your healthcare professional at your earliest convenience.
	The code card is damaged or you are using a wrong code card.	Please contact our local agent.

8. Labeling and Information


Do not re-use


Keep dry


Use-by date


Consult instructions for use


Caution, consult accompanying documents

Store temperature limitation

Operating temperature limitation


Keep away from sunlight


Manufacturer

Serial number

Batch number

In vitro diagnostic medical device

Authorized representative in the European Community/European Union


Paper recycling

This product meets the requirements of Directive 98/79/EC in vitro diagnostic medical devices.


Please do not dispose this meter with other household or municipal waste. Please follow regulation to dispose the meter at designated recycling facility, or return it back to your original purchasing site.

Lancet CE 0197 and Lancing Device
Beijing Ruicheng Medical Supplies Co., Ltd.
No. 558 Zhangzikou, Yangsong Town,
Huairou District, 101400 Beijing, China.

EC REP

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.

VISGENEER INC.
No. 335, Sec. 6, Zhonghua Rd., 30094 Hsinchu City, Taiwan
Tel : 886-3-5181918
Fax : 886-3-5181908
E-mail : eB@visgeneer.com
Website : www.eB-monitor.com | www.visgeneer.com

CE 0123

EC REP

MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

M E M O