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Bene**Check**™ Uric Acid Monitoring System

User's Manual

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Chapter 1 BeneCheck Uric Acid Monitoring System

1.1 Introduction

Thank you for choosing BeneCheck Uric Acid Monitoring System. The BeneCheck Uric Acid Monitoring System is designed by General Life Biotechnology Co., Ltd and marketed all over the world.

The BeneCheck Uric Acid Monitoring System provides you with accurate, plasmacalibrated results based on electrochemical sensor technology. The blood uric acid level is precisely calculated and displayed in a short time.

Intended Use :

The BeneCheck Uric Acid Monitoring System is designed to measure blood uric acid levels in whole blood. The test strips are for self-testing outside the body (in vitro diagnostic use). It should be used only for testing uric acid with fresh capillary finger blood samples. The system is suitable for users to monitoring their Uric Acid at home by themselves and also can be used at clinical sites by healthcare professionals to test the blood uric acid levels of patients.

The BeneCheck Uric Acid Monitoring System is calibrated using venous plasma with calibrators which were referenced to NIST SRM913a and Uricase/UV method.

Please read the entire USER'S MANUAL carefully before using the BeneCheck Uric Acid Monitoring System to test your Uric Acid levels. This USER'S MANUAL guides you through the operation procedures with illustrated directions and help you find the required informations.

WARNING :

Please carefully read the instructions in this USER'S MANUAL and become familiar with the test procedures before using the system to test Uric Acid level. User should consult with a healthcare professional before going ahead important medical decision.

1.2 Contents of the Kit

Please check the whole package for the BeneCheck Uric Acid Monitoring System. The system includes the following items :

BeneCheck Uric Acid Meter BeneCheck Uric Acid User's Manual Kit Carrying Bag

Optional :

BeneCheck Uric Acid Test Strip (vial) BeneCheck Uric Acid Test Strip Instruction BeneCheck Uric Acid Control Solution Lancing Device (Manufacturer : refer to the label on the package) Lancets (Manufacturer : refer to the label on the package)

1.3 Labelling and Informations

limitation

Do not re-use

Keep dry



Keep away from sunlight

Operation temperature

Operation 10°C

Storage -30°C

Storage temperature limitation

CE $_{0197}$ CE certification

Manufacturer





Read instructions

Caution, consult accompanying documents

REP EU Representative

EC

REF

IVD

LOT

Catalogue number (Product number)

In-vitro diagnostic

Lot number

1.4 System Components Meter (Front Side)

BeneCheck" UA

Test Port : Where you insert the test strip for test.

LCD Screen :

for display of operating information and test results.

Front Button : for on and memory mode operation.



Code Strip (Front View)

Contact Bar : Insert this end into the Test Port of the meter. Test Mode Code Number

Test Mode : UA - Uric Acid

Chapter 2 Setting-up the Meter

2.1 Installing/Replacing the Batteries

A 3-volt lithium battery (CR2032) is included in the meter package. Use only 3V lithium batteries. Do not use or replace the battery with different types of batteries. Doing so will damage the electronics of the meter.

Instructions :



Hold the meter with one hand, slightly lift the back cover lid to open the back cover.



Insert a new battery in the meter with the "+" side facing up, you will hear a "beep" sound which indicates that meter is on.



3.

Please back the cover onto the meter.

2.2 Set the Year/Month/Day/Hour/Minute/Measurement unit

The directions to setting mode.

Open the battery cover (on the back of the meter), press the setting button then a number such "2008" will blink on screen, which means Year.



Set the Year

- .. Press the front button to advance one year until you get a correct year number.
- 2. After you set the desired year number, press the back setting button again then the meter enters into month setting.



Set the Month

1. Press and release the front button until the correct month appears.



Set the Day



ΠA

UΑ

8:08AM

1 9/ 18

1. Press and release the front button until the correct day appears. 2. Press the setting button and hour segment starts blinking.



Set the Hour

- 1. Press and release the front button until the correct hour appears.
- 2. Press the setting button and minute segment start blinking. 8:88**

Set the Minute

- 1. Press and release the front button until the correct minute appears.
- Press the setting button and Measurement unit (mg/dL or mmol/L) starts blinking.





Set the Measurement Unit

- Press and release the front button until to select the unit of mg/dL or mmol/L.
- 2. Press the setting button once will finish the setting and turns off autmatically.

Note :

 The setting items of the meter is listed as follows. Please be careful to set the desired uric acid unit.

2.3 Coding the Meter

The BeneCheck Uric Acid Meter should be coded before testing with BeneCheck Uric Acid Test Strips for the first time, or every time a new box of BeneCheck Uric Acid Test Strips is used. Each vial of test strips has an assigned code number. The code strip is packaged with the test strip in order to calibrate/code the meter. Every time a test strip is inserted, please be sure to check the code number appearing on the screen is the same as the code number marked on the test strip vial.

Directions :

2.



Check the code number on the code strip is the same as the code number on the test strip vial.



Insert code strip into the test port of the meter.



3.

4.

Wait for the code number to appear on the screen.



Make sure the code number on the screen is the same as the code number on the code strip. Remove the code strip. "©" should appear on the screen,

indicating that the meter has been coded.

Cautions :



If "E-0" appears on the screen after removing the code strip, there may be a problem with the code strip. Perform the coding again, and if "E-0" continues to appear, please contact the original dealer or supplier for service.

2.4 Control Test

A control solution is used to check the performance of the BeneCheck Uric Acid Monitoring System, including BeneCheck Uric Acid Meter, BeneCheck Uric Acid Test Strip, and the user's operating skill. The system performs adequately if the control test result falls within the indicated control range listed on the test strip vial.

The system should be checked

- When you get the meter for the first time or begin using a new vial of test strip.
- When you suspect that the meter or the test strips are not working properly.
- Any time the Uric Acid test results are not consistent with how you feel, or any time you think your results are not accurate.
- Any time you drop or bump the meter.
- Upon the advice of the healthcare professional.

Directions :



Insert a test strip and immediately cover the vial to keep the other test strips in dry condition. The meter will turn on automatically.



After "CH" and " To appear on the screen, the ambient temperature and code number will follow. Be careful to make sure the code number is the same as the code number marked on test strip vial.



A blood drop symbol " 👌 " blinking on the screen means the system is ready for sample loading.



Please shake well and discard the first three drops of control solution, then drop some control solution onto a clean surface.



Touch the sample inlet of the test strip to the drop of control solution until the meter sounds a "beep". The screen will display a countdown.



6.

After count down and the screen will display the control test results. Compare the results to the control range listed on the test strip vial.

Note :

- Newly opened vials of control solution and test strips must be marked with the opening date.
- Close the test strip vial cap immediately after taking out the strip.
- Do not use BeneCheck Uric Acid Monitoring System to do any test until you can get the control test result falls within the range listed on the test strip vial.
- If the test results fall outside the control range, please refer to Chapter 8 for trouble shooting.

Chapter 3 How to perform a Uric Acid Test

3.1 Before Testing

Please follow the step-by-step instructions to ensure accurate test results. Materials required to perform a Uric Acid test include :

- BeneCheck Uric Acid Meter
- BeneCheck Uric Acid Test Strip
- Lancing Device / Lancet
- Tissue or cotton ball with 75% ethanol for wiping blood sampling area before test, or simply wash hands with soap and water thoroughly before and after test for disinfection.

Directions :



Take a test strip and immediately cover the vial cap to keep the other test strips in dry condition.



Fully insert the contact bar of the test strip into the test port of the meter. The meter will turn on automatically.



After " CH " and " $\blacksquare \blacksquare$ " appear on the screen, the code number will follow.



Check the code number on the screen is the same as the one on the test strip vial. If not, remove the test strip and recode the meter.

Note :

- The Uric Acid test must be performed within 3 minutes, otherwise the meter will be turned off automatically. If turned off, remove and re-insert the test strip to do the test again.
- Test strips cannot be reused. If a used test strip is inserted, a warning message " E-U " will display on the screen. Always use new test strips.
- If the wrong end of the test strip is inserted, or if the test Strip is inserted backwards the Meter will not activate.



Warning :

Lancet cannot be reused.

• Please always use certified lancets to ensure safety.

3.2 Perform the Uric Acid Test

Directions :



Insert the BeneCheck Uric Acid Test Strip and take a blood sample according to the instructions for lancing device in the system.



Touch the sample inlet of the test strip to the drop of blood sample until the meter sounds a "beep" that means the sample is drawn into the strip successfully.



The screen will display a countdown then display the test results after the countdown.

Note :

- Please complete the test procedures within 3 minutes or the meter will automatically turn off.
- Do not apply the blood sample on the test strip anywhere other than the sample inlet.
- Do not apply the blood sample to a same test strip twice, it will cause inaccurate test results.

3.3 Care after the Test Directions :

- 1. Follow the instructions for lancing device to treat and discard the used disposable lancet into an appropriate sharps or biohazard container.
- 2. After performing a test, remove the test strip and meter will automatically turned off.
- 3. Record the test result and date in your personal record diary.

Note :

- Please check your system performance regularly or when you suspect your test result is inaccurate.
- Dropping, bumping or other violent impact may damage the meter or cause malfunction.
- Do not use the meter in an environment with possible magnetic, electromagnetic, and radioactive interferences.

Warning :

- Do not disassemble the meter for any reason.
- Please follows local regulations to discard used test strips and lancets.
- Used test strips, lancets and any other materials which have been in contact with blood should be treated as potential biohazards. If a user has an infectious disease, the used test strips and other materials could be sources of infection.

Chapter 4 Meter Memory Function

The BeneCheck Uric Acid Meter automatically stores up to 180 records, both uric acid and control test results, each time a test is performed. The memory counts up from M01 through M180. Please follow these directions to recall stored test results.

Directions :

- 1. Make sure that no test strip is inserted in the meter.
- 2. Press the "Front Button" once to turn the meter on. A full display will appear on screen after a short "beep" sound.
- 3. Press the "Front Button" once again after the code number appears .The latest stored result M01 appears on the screen. The memory number increases progressively each time the button is pressed till M180.
- 4. Press and hold the "Front Button" will appear the stored memory continuously.
- 5. To turn the meter off, press the "Setting Button" of back side for over 5 seconds and the meter will make a long "beep" sound. The meter will also automatically shut down after 1 minutes.

Chapter 5 Storage and Handling of Meter and Strips

Due to sensitive to heat and humidity, the performance of test strips may be affected by improper storage and handling. Please store the test strips and meter carefully according to the specifications listed in Chapter 8.

Note:

- 1. Store the meter, code strip, test strips and control solution at room temperature(10 - 30°C, 50 - 86°F). Do not expose them beyond the range described in Chapter 8.
- 2. Do not freeze or refrigerate the meter and strips.
- 3. Keep the meter clean by wiping the exterior of the meter with a tissue or lintfree cloth.

Chapter 6 Icon and Alert Tones



6.2 Alert Tones

- Normal Alert Sound : a short "beep"
- Warning Alert Sound : 3 short "beeps"
- Turning On/Off Alert Sound : a long "beep"

Chapter 7 Error Message and Trouble Shooting

Message	Cause	Solution	Message	Cause	Solution
E-0	There may be a problem with the meter or code strip.	Reload the code strip or repeat the test with a new test strip. If the problem persists, please call your	E-b	The power of the battery is too low to run a test.	Replace the battery at once.
		local authorized supplier for service.	E-1	Incompatible code strip with the meter.	Reload the code strip. If the problem persists, please contact your local
E-9	The test may be interrupted after applying	Please don't remove the strip before the test is completed.			supplier for service.
blood to the strip.	blood to the strip.		E-t & T° Icon	The temperature was below or above the system	Repeat the test after the meter and the test strip have reached the
E-A	There is a problem with the meter.	Review the instructions and try again with a new test strip. If the problem persists,please call local authorized distributor for service.		operating range.	temperature within the operating range.
			E-U	It could be caused by a used test strip or a temporary or permanent electronic problem.	Repeat the test with a new test strip. If the error message appears again, please contact the dealer for service.

Message	Cause	Solution
Hi	 Blood uric acid level is higher than 20 mg/dL. (or 1.19 mmol/L) A potential problem with the test strip. 	 Review the instructions and try again with a new test strip. Check the test strip vial to make sure that it is not marked beyond the expiration date.
Lo	1.Blood uric acid level is lower than 3 mg/dL. (or 0.18 mmol/L)	 Review the instructions and try again with a new test strip. Check the test strip vial to make

2.A potential problem with the test strip.

again with a new test strip.2.Check the test strip vial to make sure that it is not marked beyond the expiration date.

Chapter 8 Specifications

System Accuracy $\pm 20\%$ at Uric Acid ≥ 5 mg/dL (0.30 mmol/L) Test Sample : Capillary whole blood Measuring Time : Within 15 seconds Measuring Range : 3 - 20 mg/dL (0.18 - 1.19 mmol/L) Sample Volume : ≥ 0.7 µL **Strip Storage Condition :** 10 - 30°C **Operation Temperature :** 10 - 40°C **Relative Humidity** : Less than 95% Memory : 180 test results Battery Type : 3V (CR2032) lithium battery x 1 **Battery Life** : Approximately 1,000 tests Dimensions : 61*77*19 mm Weight : About 47g (batteries not included)

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Chapter 9 Limitations

Please observe the following limitations for obtaining accurate results of BeneCheck Uric Acid Monitoring System :

- 1. For In-vitro diagnostic use only (External use only).
- 2. Do not dispose test strips in high humidity or direct sunlight. Don't freeze the strips.
- 3. BeneCheck Uric Acid Test Strip is for single use only, please do not reuse the test strip.
- 4. Handle the strip with clean and dry hands; lancing site for the test should be cleaned and dried thoroughly.
- 5. Do not perform the test while a cell phone is used beside; prevent the electronic signal interference.

6. Hematocrit (Hct) range from 30-55% is acceptable. Hct less than 30% may cause elevated results. Hct above 55% may cause reduced uric acid results versus a whole blood reference.