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CE 0197 REF PP-E018

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# BeneCheck™
Multi-Monitoring System
**PLUS**
# User's Manual

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# Chapter 1 BeneCheck PLUS Multi-Monitoring System

## 1.1 Introduction

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

The BeneCheck PLUS Multi-Monitoring System provides you with accurate, plasma-calibrated results based on electrochemical sensor technology. This system includes blood glucose, uric acid and total cholesterol level tests, precisely measured and displayed within 10, 15 and 30-40 seconds respectively.

**Intended Use :**

The BeneCheck PLUS Multi-Monitoring System is designed to measure the blood glucose, uric acid or total cholesterol 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 glucose, uric acid or total cholesterol with fresh capillary finger blood samples. The system is suitable for users to monitor their blood glucose, uric acid or total cholesterol at home by themselves and be used for clinical sites by healthcare professionals to test the blood glucose, uric acid or total cholesterol levels of patients.

The BeneCheck PLUS Multi-Monitoring System includes glucose, uric acid, and total cholesterol tests which are all calibrated by J&J DT60 Analyzer (Kodak EKTACHEM DT60 Analyzer) using venous plasma. The DT60 Analyzer is calibrated by VITROS DT calibrators which were referenced to the following standard and method :

| Test | Standard | Method |
|---|---|---|
| Glucose | NIST SRM 917b | AACC/CDC (Hexokinase/G6PDH) |
| Uric Acid | NIST SRM 913a | Uricase/UV |
| Total Cholesterol | NIST SRM 911b | Abell/Kendall |

Please read the entire USER'S MANUAL carefully before using the BeneCheck PLUS Multi-Monitoring system to test your blood glucose, uric acid or total cholesterol levels. This USER'S MANUAL guides you through the operation procedures with illustrated directions and help you find the required information.

**WARNING :**
Please carefully read the instructions in this user's manual and become familiar with the test procedures before using the system to test blood glucose, uric acid or total cholesterol levels. Users 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 PLUS Multi-Monitoring System. The system includes the following items :

| Item No. | Description | Quantity |
|---|---|---|
| PD-G001-1 | BeneCheck PLUS Meter | 1 |
| PD-A041 | BeneCheck PLUS Glucose Test Strip x (10pcs/vial) | 1 |
| PD-D001 | BeneCheck PLUS Uric Acid Test Strip x (10pcs/vial) | 1 |
| PD-E001 | BeneCheck PLUS Total Cholesterol Test Strip x (5pcs/vial) | 1 |
| PD-A020 | Code Strip (Glucose x 1, Uric acid x 1, Total Cholesterol x 1) | 1 |
| PD-F004 | Glucose Control Solution x 1 | 1 |
| PP-E018 | BeneCheck PLUS User's Manual | 1 |
| PP-E019 | BeneCheck PLUS Glucose Test Strip Instruction | 1 |
| PP-E020 | BeneCheck PLUS Uric Acid Test Strip Instruction | 1 |
| PP-E021 | BeneCheck PLUS Total Cholesterol Test Strip Instruction | 1 |
| PP-E023 | Glucose Control Solution Instruction | 1 |
| PD-A006 | Lithium Battery 3V (CR2032) | 1 |
| PD-A019 | Kit Carrying Bag | 1 |
| PD-A015 | Lancing Device | 1 |

| Item No. | Description | Quantity |
|---|---|---|
| PD-A018 | Lancets (pack)<br>(Manufacturers of Lancing Device and Lancet : For detail information, please refer to inside package. ) | 1 |

**Optional :** ( not included in the standard kit package, please contact your local distributor for ordering. )

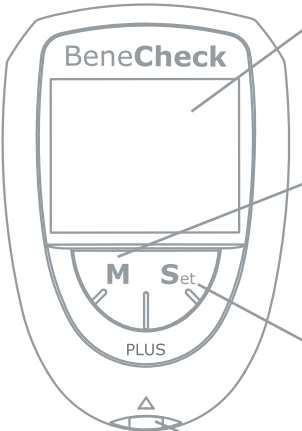
| | |
|---|---|
| BeneCheck PLUS Glucose Test Strip | BKP-G-S001 |
| BeneCheck PLUS Uric Acid Test Strip | BKP-U-S001 |
| BeneCheck PLUS Total Cholesterol Test Strip | BKP-C-S001 |

## 1.3 Labelling and Information

| | | | |
|---|---|---|---|
|  | Do not re-use |  | Use by |
|  | Keep dry |  | Read instructions |
|  | Keep away from sunlight |  | Caution, consult accompanying documents |
|   | Operation temperature limitation | EC REP | EU Representative |
|   | Storage temperature limitation | REF | Catalogue number (Product number) |
| CE 0197 | CE certification | IVD | In-vitro diagnostic |
|  | Manufactured by | LOT | Lot number |

## 1.4 System Components

### Meter (Front Side)




**LCD Screen** :
For display of operating information and test results.

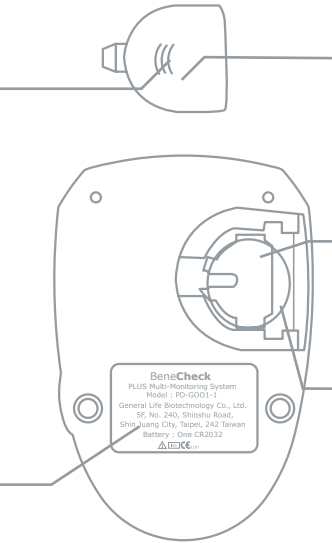
**Left "M" Button :**
For memory mode operation.

**Right "Set" Button :**
For on/off and setup mode operation.

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

## Meter (Back Side)

**Battery Cover Lid :**
Pull right ward to remove the cover when replacing battery




**Battery Cover :**
For covering the battery.

**Battery Socket :**
For holding a 3V-lithium battery

**Battery :**
3V lithium battery (CR2032)

**Tag :**
Display information about the meter.

**Test Strip**
**Glucose & Uric Acid Strip**

**Electronic Contact Bar :**
Insert Electronic Contact Bar of the test strip into the Test Port of the meter to activate it.


**Sample Inlet :**
The inlet where the whole blood or control solution is drawn in. Touching a blood sample or control solution will result in a capillary action automatically

**Total Cholesterol Strip**

**Electronic Contact Bar :**
Insert Electronic Contact Bar of the test strip into the Test Port of the meter to activate it.

**Reaction Zone :**
Reaction zone of Total Cholesterol


**Sample Inlet :**
The inlet where the whole blood or control solution is drawn in. When a blood sample or control solution touches this end, the sample will be sucked into the reaction zone automatically. The reaction zone of total cholesterol strip full of control solution or a blood sample at least 10 μL is essential.

**Code Strip** ( Front View )

**Contact Bar :**
Insert this end into the Test Port of the meter.


**Code Number**

**Test Mode**

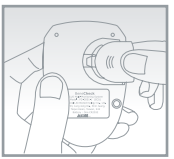
**Test Mode :**
**GLUC - Glucose**
**UA - Uric Acid**
**CHOL - Total Cholesterol**

# Chapter 2 Setting-up the Meter

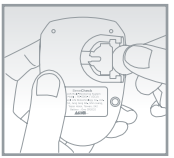
## 2.1 Installing/Replacing the Battery

Battery is loaded inside the meter. Use only 3V lithium battery. Do not use or replace the battery with different types of battery which will damage the electronics of meter.

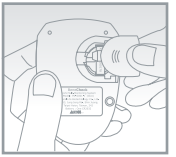
**Instructions :**

1. 

Hold the meter with one hand, slightly pull right the back cover to remove the back cover.

2. 

Insert a new battery to the battery socket with the "+" side facing up.

3.  Place back the battery cover onto the meter.

### 2.2 Set the Year/Month/Day/Hour/Minute

Press and hold the "Set" button for over two seconds, the meter will sound one beep and enter the setting mode. Please follow the directions below to set the meter.

Under the setup mode, the LCD screen of the meter shows all setting items start from a blinking year "200X" and the rest setting items are listed as follows:


**Set the Year**

1. When the meter enter setting mode, the first item on the screen such as "2008" will blink on screen, which means Year.
2. Click the left "M" button to advance one year until you get a correct year number.
3. After you set the desired year number, click the "Set" button again then the meter enters into month setting.


**Set the Month**

1. Click the left "M" button until the correct month appears.
2. Click the right "Set" button, and then day segment starts blinking.


**Set the Day**

1. Click left "M" button until the correct day appears.
2. Click the right "Set" button, and the hour segment will start blinking.


**Set the Hour**

1. Click left "M" button until the correct hour appears.
2. Click the right "Set" button, and the minute segment will start blinking.


**Set the Minute**

1. Click left "M" button until the correct minute appears.
2. Click the right "Set" button then measurement unit segment starts blinking.

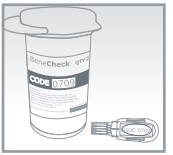
After you finish setting the meter, press the right "Set" button, and the the meter will show "OFF" on the screen and power-off.

**Note :**
Please refer to Chapter 5 for the measurement units setting procedure.

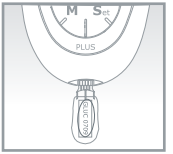
## 2.3 Coding the Meter

The BeneCheck PLUS meter should be coded before testing with BeneCheck PLUS test strips for the first time, or every time a new box of BeneCheck PLUS test strips are used. There are three kinds of test strips which can be used with BeneCheck PLUS meter. Each vial of the test strips has assigned a code number and test mode. The code strip is packaged with the test strip in order to calibrate/ code the meter. Every time a test strip is inserted, please check the code number and test mode appearing on the Screen is the same as the code number and test mode marked on the code strip and test strip vial.

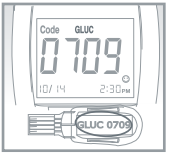
**Directions :**
**For Glucose Test Mode**

1. 

Check the code number and test mode on the code strip is the same as the code number and test mode on the glucose test strip vial, and check the test mode of the strip.

2. 

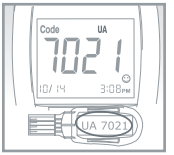

Insert a code strip into the test port of the meter.
Wait for the code number to appear on the screen.

3. 


Make sure the code number on the screen is the same as the code number on the code strip, and the test mode is also the same as marked on the test vial.
Remove the code strip. "☺" should appear on the screen, indicating that the meter has been successfully coded to glucose test mode.

**For Uric Acid Test Mode**

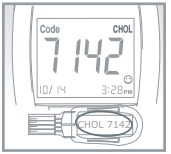
Follow the same procedures of 1 to 3 described in glucose test mode .

4. 


Make sure to check that the code number and test mode on the code strip are the same as the code number and test mode on the uric acid test strip vial.
Remove the code strip. "☺" should appear on the screen, indicating that the meter has been successfully coded to uric acid test mode.

**For Total Cholesterol Test Mode**

Following the same procedures of 1 to 3 described in glucose test mode .

5. 


Make sure to check the code number and test mode on the code strip is the same as the code number and test mode on the total cholesterol test strip vial.

Remove the code strip. "☺" should appear on the screen, indicating that the meter has been successfully coded to total cholesterol test mode.

**Cautions :**

If "E-E" appears on the Screen during coding procedure, there may be a problem with the code strip or a wrong category code strip may be misused. Perform the coding procedures again, and if "E-E" continues to appear, please contact the authorized distributor for service.

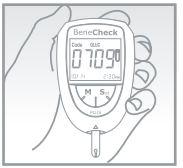
## 2.4 Control Test

The purpose of control solution is used to check the performance of the BeneCheck PLUS System. The system and strips perform adequately if the control test result falls within the indicated control range listed on the test strip vial.

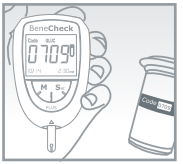
The system should be checked

- When you get your meter for the first time or begin using a new box of test strips.
- When you suspect that the meter or the test strips are not working properly.
- Any time you had repeated unexpected test results of the blood glucose, uric acid or total cholesterol.
- Any time you drop or bump the meter.
- You can check system performance regularly or anytime by using control solution when you suspect that test results are inaccurate.

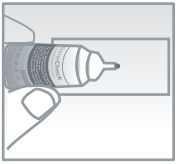
**Directions :**

1. 

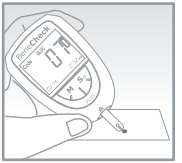

Insert a test strip into test port, the meter will turn on automatically.

2. 

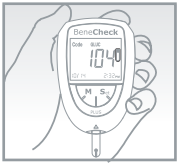

The code number and test mode will be shown on the screen. Be careful to make sure the code number and test mode is the same as the code number marked on test strip vial.

3. 

A blood drop symbol "" blinking on the screen means the system is ready for sample loading.
Shake the control solution vial vigorously, then open the cap to discard the first three drops, after wiping the dispense tip and cleaning with tissue, then drop some control solution onto a clean object such as transparency.

4. 


Touch the sample inlet of the glucose, uric acid or total cholesterol test strip to the drop of control solution until the meter sounds a “beep”. The screen will display a countdown from 10 seconds for glucose test strip, 15 seconds uric acid test strip, and 26 seconds for total cholesterol test strip.

5. 


After counting down, the screen will display the control solutions test results. Compare the test results to the control range listed on the test strip vial.

**Note :**

- Please read this user's manual and instructions for control solution test carefully before use.
- Do not reuse the test strips and always close the cap of test strip vial tightly after used.
- The first three drops of control solution must be discarded and the vial should be shaken well before use when the vial is newly opened.
- Newly opened vials of control solution and test strips must be marked with an opening date.
- Do not use BeneCheck PLUS Multi-Monitoring System to do any test until you can get the control test result to fall within the control range listed on the test strip vial.
- The test results fall outside the control range, please reconfirm and repeat the test, if it still fall outside the range, please contact an authorized distributor for help and service.
- Uric acid control solutions and total cholesterol control solutions are not included. Please contact an authorized distributor for ordering.

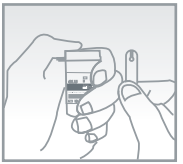
## Chapter 3 How to perform a Test

### 3.1 Before Testing

Please follow the step-by-step instructions to ensure accurate test results.
Materials required to perform a blood glucose, uric acid or total cholesterol test include :

- BeneCheck PLUS Meter
- BeneCheck PLUS Glucose, Uric Acid or Total Cholesterol Test Strip
- Lancing Device
- Lancet
- Tissue or cotton ball with 75% ethanol for wiping blood sampling area, or washed with soap and water before and after test for disinfection.

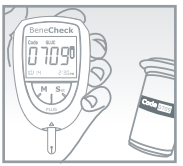
**Directions :**
Load the lancing device with a lancet and adjust suitable penetration depth.
Use warm soap water to wash your hands. Rinse and dry thoroughly.

1. 

In order to keep the test strips in dry preservation, please put the lid immediately on the vial after you take test strip out.

2. 


Fully insert the contact bar of the test strip into the test port of the meter. The meter will turn on automatically with test mode display and code number appear on the Screen.

3. 


Check the test mode and code number on the screen are the same as the one on the test strip vial. Icon “GLUC”, “UA” and “CHOL” indicate measuring mode of glucose, uric acid and total cholesterol respectively. If not, remove the test strip and recoding the meter is necessary as described in Section2.3.

**Note :**

- One measurement must be performed within 3 minutes, otherwise the meter turn off automatically. Please, remove and re-insert the test strip to do the measurement again.
- Do not reuse test strips. Warning Error message "E-U" will display on the screen, if a used test strip is inserted.
- If the wrong end of the test strip is inserted, or if the test strip is inserted backwards the meter will not activate.

**Warning :**

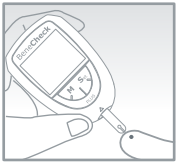
- Lancet, test strip cannot be reused.
- Please always use certified lancet to ensure safety.

### 3.2 Testing procedure for Blood Glucose

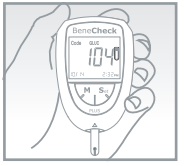
**Directions :**

1. 


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

2. 


Touch the sample Inlet of the strip to the drop of blood sample until the meter sounds a "beep", which means the sample has drawn into strip successfully.

3. 


The screen will display a count down from 10 seconds. After 10 seconds the Screen will display the blood glucose results.

**Note :**

- Be sure to wipe off the first drop of blood to avoid body fluid contamination.

### 3.3 Testing procedure for Uric Acid

1. Insert the BeneCheck PLUS Uric Acid Test Strip and take a blood sample according to the instructions for lancing device in the system.
2. Touch the sample inlet of the strip to the drop of blood sample until the meter sounds a “beep” which means the sample has been drawn into strip successfully.
3. The screen will display a count down from 15 seconds. After 15 seconds the screen will display the blood uric acid results.

### 3.4 Testing procedures for Total Cholesterol

1. Insert the BeneCheck PLUS Total Cholesterol Test Strip and take a blood sample according to the instructions for lancing device in the system.
2. Make sure to get enough blood sample volume.
3. Touch the sample inlet of the strip blood sample until the reaction zone has been full of enough amount of blood sample after that a "beep" sound will be heared accordingly.
4. The screen will display a count down from the required test 26 seconds. After counting down the screen will display the blood total cholesterol result.

**Note :**

- The BeneCheck PLUS Multi-Monitoring System includes glucose, uric acid and total cholesterol test that are all plasma calibrated. The user does not have to convert it into plasma result.
- Use the strips before the expired date, the strips can only be used within 3 months remaining shelf life after the first opening of the vial.
- Apply the blood sample onto the correct position of the strip precisely, follow the directions to familiar with correct operation.
- Prohibited applying the blood sample to the test strip twice, it will cause inaccurate test results.

**Special Messages :**

| | **Messages** | |
|---|---|---|
| Mode | Lo | Hi |
| Glucose | < 20 mg/dL (1.11 mmol/L) | > 600 mg/dL (33.3 mmol/L) |
| Uric Acid | < 3 mg/dL (0.18 mmol/L) | > 20 mg/dL (1.19 mmol/L) |
| Total Cholesterol | < 100 mg/dL (2.59 mmol/L) | > 400 mg/dL (10.35 mmol/L) |

### 3.5 Care after the Test

**Directions :**

1. Improper usage of the meter, such as dropping, bumping or other violent impact may cause the meter damaged.
2. Please keep meter away by interferences of magnetic, electromagnetic, and radioactive.

**Warning :**

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

## Chapter 4 Meter Memory Function

The BeneCheck PLUS Meter automatically stores up to 460 test results, which includes all the blood glucose 360, uric acid 50 and total cholesterol 50 test results and control test results. It also provides you with 7-, 14-, 21- and 28-day averages of the blood glucose test results. The memory counts up from M01 through M360 for glucose test, M01 through M50 for uric acid and total cholesterol test, respectively. 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 left "M" button once to turn the Meter on. After a short "beep" sound a full display will appear on screen then the meter enters standby mode.

**Note :**

- The day average function can be applied to glucose test mode only, uric acid and total cholesterol test mode do not have the day average function.

3. Press the left "M" button once again and the meter stays at memory mode. The 7-day average (7 DAY.A) will display on the Screen.

4. Followed by 14, 21 and 28-day average when press the left "M" button repeatedly.
5. After the 28day-average, the latest stored result M01 appears on the screen. The memory number increases progressively each time the button is pressed untill M360.
6. Press the left "M" button for over 3 seconds and the meter will turn off after a long "beep" sound. Meter will also automatically shut down after 3 minutes without any operation.

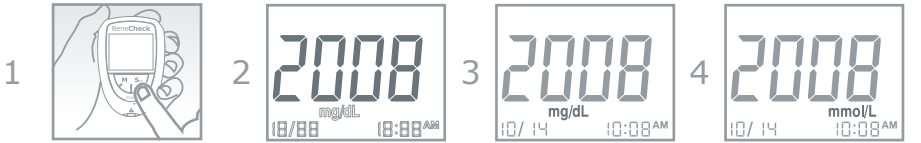
**Note :**

- If 360 test results are already stored and a new one is added, the oldest test result is automatically overwrited. The newest result will be shown in M01.

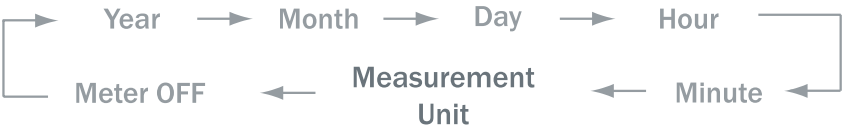
## Chapter 5 How to Set the Measurement Units

**Directions :**

1. Make sure that no test strip is inserted in the meter.
2. Press and hold the "Set" button for over 2 seconds, the meter will sound beep (Fig. 1).




The sequence of the setup mode is indicated as below :



3. Click the right "Set" button for six times, and a blinking "mg/dL" will display on the screen.
4. Pressing the “M” button will switch the unit of measure between "mg/dL" and "mmol/L" (See Fig.3&4)
5. Click the right “Set” button once again the meter will turn off.

**Note :**
- Before each test, please make sure correct unit of the measure is set up.

## Chapter 6 Storage and Handling of Meter and Strips

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 9.

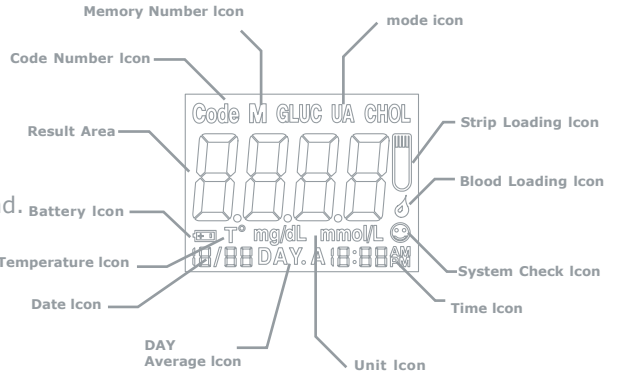
Note:

- Store the meter, code strip, test strips and control solution at 10-30°C.
- Do not store test strips in high humidity enviroment or dispose under direct sunlight.
- Do not freeze or refrigerate the meter and strips.
- Keep the meter clean by wiping the exterior appearance of the meter with a tissues or lint-free cloth.
- Handle the strip with clean and dry hands; lancing site for the test should be cleaned and dried thoroughly.

# Chapter 7 Icon and Alert Tones

## 7.1 Icon on the Screen

The vivid and clear information icons on the Screen are helpful and convenient, the icon design are easy to understand.




## 7.2 Alert Tones

- Normal Alert Sound : a short “beep”
- Warning Alert Sound : 5 short “beeps”
- Turning On/Off Alert Sound : a long “beep”

## Chapter 8 Error Message and Trouble Shooting

| Message | Cause | Solution |
|---|---|---|
| E-0 | There will be a problem with the test strip. | Repeat the test with a new test strip. If the problem persists, please contact the dealer for service. |
| E-b | The power of the battery is too low to run a test. | Replace the battery at once. |
| Err.3 | The reference voltage or other circuit is error. | Call local authorized distributor for help and service. |
| E-E | 1. There may be a problem with self-check of the meter.<br>2. Use of the wrong or damaged code strip or the code strip was inserted improperly. | Power off then retry, if the error appears again, contact the authorized distributor for service.<br>Check that the code number on the meter display matches the code number on the test strip vial. Code the meter or retest as necessary. If the error message appears again, please contact the dealer for service. |

| Message | Cause | Solution |
|---|---|---|
| E-t & Temperature Icon Sign | The temperature is below or above the system operating range. | Repeat the test after the meter and the test strip have reached at 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. |

## Chapter 9 Specifications

| | | |
|---|---|---|
| **System Accuracy** | : | ± 20% at Glucose level ≥75 mg/dL (4.17mmol/L)<br>± 20% at Uric Acid ≥ 5 mg/dL (0.30 mmol/L)<br>± 20% at Total Cholesterol ≥ 150 mg/dL |
| **Principle** | : | Glucose & Total Cholesterol - Electrochemical Biosensor ,Uric Acid - Electrochemical Sensor |
| **Calibration** | : | Plasma-equivalent |
| **Test Sample** | : | Fresh Capillary whole blood |
| **Measuring Time** | : | About 10 seconds (Glucose), 15 seconds (Uric Acid), 30 - 40 seconds (Total Cholesterol) |
| **Measuring Range** | : | Glucose 20 - 600 mg/dL (1.1 - 33.3 mmol/L)<br>Uric Acid 3 - 20 mg/dL (0.18 - 1.19 mmol/L)<br>Total Cholesterol 100 - 400 mg/dL (2.59 - 10.35 mmol/L) |
| **Sample Volume** | : | About 1 - 1.5 µL (Glucose & Uric Acid)<br>About 10 µL (Total Cholesterol) |
| **Hematocrit Range** | : | 30 - 55% (for Glucose, Uric Acid)<br>35 - 50% (for Total Cholesterol) |
| **Strip Storage Condition** | : | 10 - 30ºC (50 - 86ºF) |

| | | |
|---|---|---|
| **Operation Temperature** | : | 10 - 40ºC (50 - 104ºF) |
| **Relative Humidity** | : | Less than 95% |
| **Memory** | : | 460 test results<br>(360 for Glucose, 50 for Uric Acid, 50 for Total Cholesterol) |
| **Battery Type** | : | One 3V (CR2032) lithium battery |
| **Battery Life** | : | Approximately 1,000 tests |
| **Dimensions** | : | 86*57*17 mm (Length, Width, Height) |
| **Weight** | : | About 48 g (with battery) |

## Chapter 10 Limitations

Please observe the following limitations for obtaining accurate results of BeneCheck PLUS Multi-Monitoring System :

1. For In-vitro diagnostic use only (External use only).

2. BeneCheck PLUS Test Strip is designed for one-time use only. Do not reuse.

3. Do not perform the test while a mobile phone is used beside; prevent the electronic signal interference.

### 10.1 Limitations of Glucose Test

BeneCheck PLUS Glucose Test Strips give accurate results when the following limitations are observed :

- Hematocrit (Hct) percentage may affect test result. If Hct levels less than 30% may cause incorrect high measurement results and Hct levels greater than 55% may cause incorrect low measurement results. Please consult your medical professionals if you do not know your Hct level.

- Do not use the test strips for the testing of newborns.

- The test strips react with only D-glucose and do not react with other sugars which may be present in blood.

- Use only fresh capillary finger whole blood. Do not use serum or plasma.

- BeneCheck PLUS Glucose Test Strips may be used at altitude up to 10,000 feet without an effect on test results.

Additional Information for Healthcare Professionals :

- When venous whole blood is used for the test, it can be collected into heparin-containing test tubes winthin 30 minutes after drawing. The results may be 7% lower than a capillary sample.

- Interferences : Acetaminophen, uric acid, ascorbic acid, dopamine, gentistic acid, ibuprofen, methyl DOPA, salicylate, tetracycline, tolazamide, tolbutamide (when at physiological or therapeutical levels) do not significantly affect the results.

- Patients undergoing oxygen therapy may yield falsely low results.

- In situations of decreased peripheral blood flow, examples would include but are not limited to severe dehydration, in shock, or in a hyperosmolar state (with or without ketosis), hypertension, the test results may be falsely low.

- BeneCheck PLUS Glucose Test Strips are plasma calibrated, testing with serum or plasma sample will give falsely high results.

- BeneCheck PLUS Glucose Test Strips have not been validated for testing with

neonatal blood specimens.

- Lipemic samples : Cholesterol levels up to 400 mg/dL (10.35 mmoL/L), and triglycerides up to 3000 mg/dL (34.88 mmoL/L) do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with the BeneCheck Plus Glucose Test Strips.

- Critically ill patients should not be tested with blood glucose meters.

## 10.2 Limitations of Uric Acid Test

BeneCheck PLUS Uric Acid Test Strips give accurate results when the following limitations are observed :

- Hematocrit (Hct) percentage may affect test result. If Hct levels less than 30% may cause incorrect high measurement results and Hct levels greater than 55% may cause incorrect low measurement results. Please consult your medical professionals if you do not know your Hct level.

- Use only fresh capillary finger whole blood. Do not use serum or plasma.

- BeneCheck PLUS Uric Acid Test Strips may be used at altitude up to 10,000 feet without an effect on test results.

Additional Information for Healthcare Professionals :

- Interferences : Acetaminophen, allopurinol, amiloride, ascorbic acid, atenolol, colchicine, diclofenac, dopamine, glibenclamide, ibuprofen, indomethacin, ketoprofen, metfoemin, methyl DOPA, salicylate, tetracycline, tolazamide, tolbutamide (when at physiological or therapeutical levels) do not significantly affect the results. Gentistic acid at therapeutic levels (5 mg/dL) may give falsely

high results of uric acid test.

- In situations of decreased peripheral blood flow, examples would include but are not limited to severe dehydration, in shock, or in a hyperosmolar state (with or without ketosis), hypertension, the test results may be falsely low.

- BeneCheck PLUS Uric Acid Test Strips are plasma calibrated, test with serum or plasma sample will give falsely high results.

- Lipemic samples : Cholesterol levels up to 400 mg/dL (10.35 mmol/L) do not affect the results. Triglycerides and grossly lipemic patient samples have not been tested and are not recommended for testing with the BeneCheck PLUS Uric Acid Test Strips.

### 10.3 Limitations of Total Cholesterol Test

BeneCheck PLUS Total Cholesterol Test Strips give accurate results when the following limitations are observed :

- Hematocrit (Hct) percentage may affect test result. If Hct levels less than 35% may cause incorrect high measurement results and Hct levels greater than 50% may cause incorrect low measurement results. Please consult your medical professionals if you do not know your Hct level.

- Use only fresh capillary finger whole blood. Do not use serum or plasma.

- BeneCheck PLUS Total Cholesterol Test Strips may be used at altitude up to 8,000 feet without an effect on test results.

Additional Information for Healthcare Professionals :

- Interferences : Acetaminophen, uric acid, ascorbic acid, dopamine, gentistic acid, ibuprofen, methyl DOPA, salicylate (when at physiological or therapeutical levels) do not significantly affect the results. Hemoglobin at physiological levels ≤10 mg/dL.

- In situations of decreased peripheral blood flow, examples would include but are not limited to severe dehydration, in shock, or in a hyperosmolar state (with or without ketosis), hypertension, the test results may be falsely low.

- BeneCheck PLUS Total Cholesterol Test Strips are plasma calibrated, tests with serum or plasma sample will give falsely high results.

- Lipemic samples : Glucose levels up to 476 mg/dL (13.89 mmoL/L) do not affect the results. Triglycerides and grossly lipemic patient sample have not been tested and are not recommanded for testing with the BeneCheck PLUS Total Cholesterol Test Stirps.