



General Life Biotechnology Co., Ltd.
5F, No.240, Shinshu Rd., Shin Juang Dist.,
New Taipei City, 242 Taiwan
www.BeneCheck.com.tw
Model: BK3-12M-D

TEL : +886-2-22053698
FAX : +886-2-22080779
E-mail : service@glbiotech.com.tw



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany



Doc.#: FIG-312M-C2-101-2 Jan, 2017

BeneCheck™

Multi-Monitoring Meter

User's Manual



BK3-12M-D



Total Cholesterol

Glucose

Uric Acid

Chapter 1	BeneCheck Multi-Monitoring Meter BK3-12M-D	
1.1	Introduction.....	1
1.2	Contents of the Kit.....	2
1.3	Labelling and Information.....	3
1.4	BeneCheck Meter Kit.....	4
	LCD Screen Display and Alert Tones.....	5
	Test Strip and Code Strip.....	6
Chapter 2	Setting the Meter	
2.1	Installing/Replacing the Batteries.....	7
2.2	Set the Date and Time.....	7-8
2.3	Code the Meter.....	8
Chapter 3	How to Perform a Test	
3.1	Before Testing.....	9
3.2	Perform the Test.....	10-12
3.3	Alternate Site Testing (AST).....	12-14
3.4	Care after Testing.....	15-16
Chapter 4	Meter Memory Function.....	17-18
Chapter 5	Control Solution Test.....	19-20
Chapter 6	Transmission Function.....	21
Chapter 7	Care and Maintenance	
7.1	Storing Your Meter.....	22
7.2	Cleaning and Caring for Your Meter.....	22
Chapter 8	Error Message and Trouble Shooting.....	23-24
Chapter 9	Specification.....	25

Chapter 1 BeneCheck Multi-Monitoring Meter BK3-12M-D

1.1 Introduction

Thank you for choosing BeneCheck. BeneCheck Multi-Monitoring Meter BK3-12M-D (meter) is based on electrochemical biosensor technology, which can check your blood glucose (GLU), total cholesterol (CHOL), and uric acid (UA) fast and convenient.

Please read this user's manual carefully before using this product. If you need any further assistance, please contact your local customer service.

Intended Use:

The meter is used to measure Blood Glucose in fresh capillary whole blood from fingertip, palm, or forearm, and Total Cholesterol and Uric Acid from fresh fingertip capillary whole blood. The meter is only for *in vitro* diagnostic use. The meter can be used by lay persons at home or patients tested by healthcare professional.

The meter is plasma-calibrated by reference instruments which are traceable to the following standard reference materials and methods.

Test	Standard	Method
Glucose	NIST SRM 917c	Glucose Oxidase
Total Cholesterol	NIST SRM 911b	Abell / Kendall
Uric Acid	NIST SRM 913a	Uricase / UV

WARNING :

Please carefully read the instructions and test procedures in this user's manual before using. Users should consult healthcare professional before making any important medical decision.

1.2 Contents of the Kit




















The items included in BeneCheck Meter Kit:
(please check the meter outer box for exact detail)

Description	Quantity
BeneCheck Multi-Monitoring Meter (Model: BK3-12M-D) (with a CR2032 3V battery)	1
User's Manual	1
Quick Guide	1
Kit Carrying Bag	1

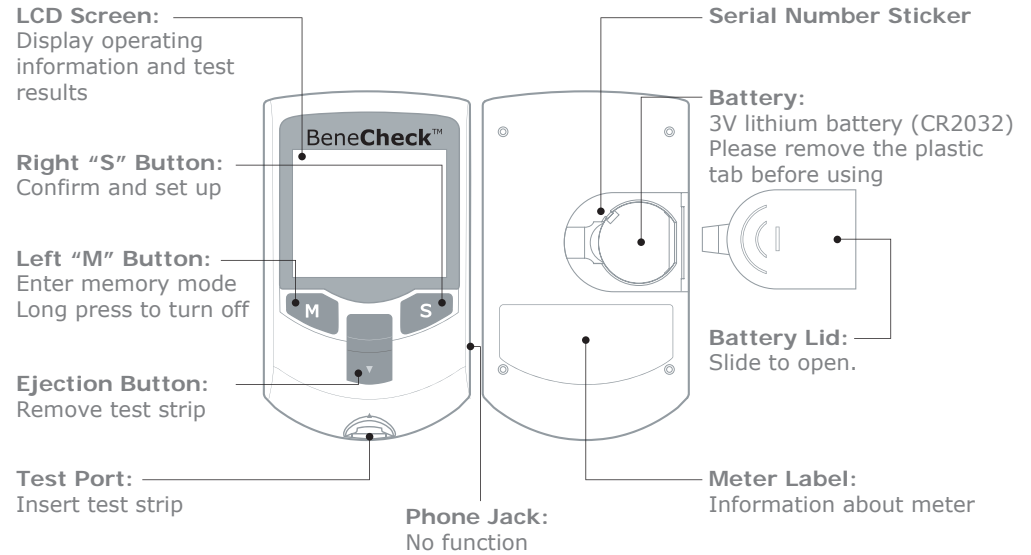
Optional : (not included in the standard kit package, please contact your local distributor for ordering.)

BeneCheck Glucose Test Strip (Model: BK3-G) (with Insert)
BeneCheck Total Cholesterol Test Strip (Model: BK-C2) (with Code Strip and Insert)
BeneCheck Uric Acid Test Strip (Model: BK-U1) (with Code Strip and Insert)
BeneCheck II Glucose Control Solution
BeneCheck II Total Cholesterol Control Solution
BeneCheck Uric Acid Control Solution
Lancing Device
Lancets (pack) (Manufacturer: For detail information, please refer to inside package.)

1.3 Labelling and Information

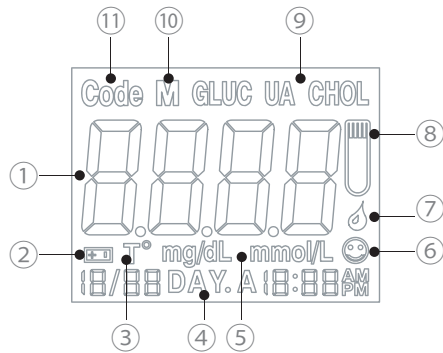
	Use by		<i>In-vitro</i> diagnostic
	Manufactured by		Lot number
	Do not reuse		Date of Manufacture
	Keep dry		Serial number
	Keep away from sunlight		Operation temperature limitation
	Read instructions		Operation Relative Humidity
	Caution, consult accompanying documents		Storage & Transportation Condition
	EU Representative		Storage & Transportation Relative Humidity
	Comply with WEEE Directive 2012/19/EU		CE certification
	Ingress Protection		

1.4 BeneCheck Meter Kit Meter (Front Side & Back Side)



LCD Screen Display:

Information and test result display



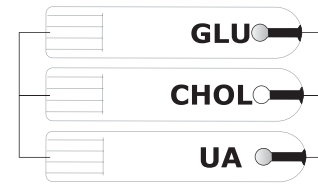
- ① Result Area
- ② Low Battery
- ③ Temperature Icon
- ④ Average (GLU)
- ⑤ Unit Icon
- ⑥ System Check
- ⑦ Blood Loading Icon
- ⑧ Strip Loading Icon
- ⑨ Test Mode Icon
- ⑩ Memory Mode Icon
- ⑪ Code Number Icon

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

Test Strip:

- GLU-** Glucose
- CHOL-** Total Cholesterol
- UA-** Uric Acid

Electronic Contact Bars:
Insert this end into meter test port.

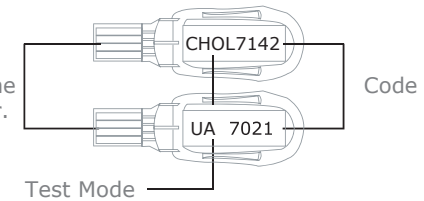


Sample Inlet:
The whole blood sample and control solution will be drawn from here.

Code Strip:

The code strip is used to code the meter.
Please do the coding step when you use a new vial of CHOL or UA strip.

Contact Bar :
Insert this end into the test port of the meter.

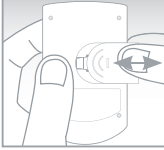
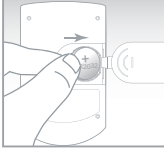


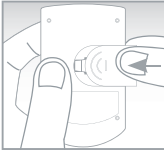
Chapter 2 Setting the Meter

2.1 Installing/Replacing the Batteries

Please remove the plastic tab under the battery before using. This meter uses a CR2032 battery. Do not use or install different types of battery. It will damage the meter.

Installing Instructions:

-  • Slide to remove the battery lid.
-  • Insert the battery with the positive (+) side up.

-  • Slide back the battery lid.

Note: Dispose the batteries according to your local environmental regulations.

2.2 Set the Date and Time

Press "S" button for over three seconds. You will hear one "beep" for entering the setting mode, then follow the instruction below to set up.

Setting order: Year/Month/Date/Hour/Minute


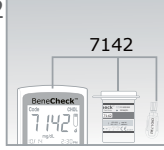
- Click "M" button to advance one unit.
- Click "S" button to enter next setting.
- The meter will turn off automatically after setting.



Note: Adjust the correct time and date is important to help managing your health records.

2.3 Code the Meter

Each vial of CHOL or UA strip has a code strip to code your meter. Code your meter when you first use it or open a new vial of strips. With the Auto Strip Recognition function, once you code your meter, you do not have to switch the test mode with code card every time you perform a test.

-  • Make sure the meter is off.
• Then insert the code strip into the test port.
-  • The code number will show on the screen. Make sure the numbers on screen, code strip, and strip vial label are the same.
• Then remove the code strip.

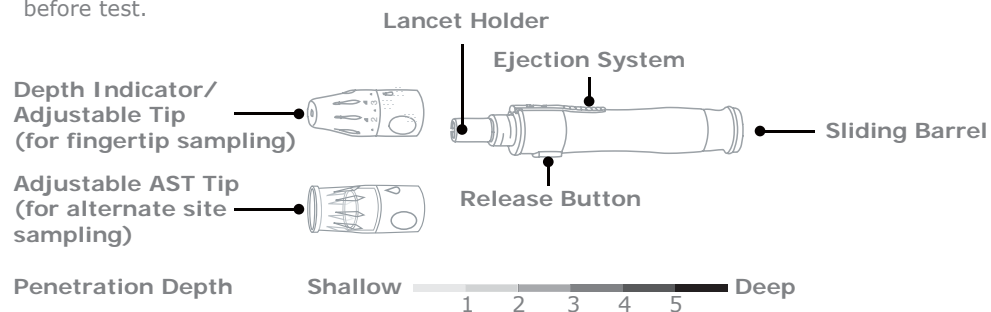
Chapter 3 How to Perform a Test

Please follow the instruction carefully to ensure an accurate test result.

3.1 Before Testing

Materials you need to perform a test:

- BeneCheck Meter
- BeneCheck Test Strip
- Lancing Device/ Lancets
- Tissue or cotton ball with 75% ethanol or disinfection wipes for cleaning the sampling area before test.



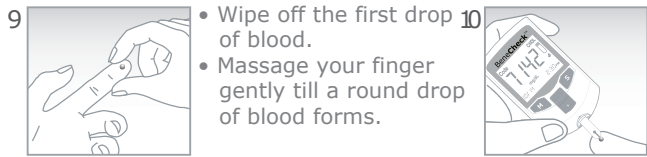
Note: Wash your hands with water and soap thoroughly before and after testing, and make sure the sampling area is dry before testing.

Beijing Riucheng Medical Supplies Co.,Ltd
Fengxiang Avenue, Fengxiang
Development Zone, Yangsong Town,
Huairou District, Beijing 101400 China
TEL: +86-10-61678701

3.2 Perform the Test

- Twist and remove the adjustable tip.
- Insert a lancet into the holder firmly.
- Twist back the tip.
- Adjust skin penetration depth by turning the front end.
- Insert the strip contact bar into meter test port.
 - The meter will turn on automatically.
- Make sure the code numbers are the same on screen and strip vial label in CHOL or UA test.
 - You can start testing after " " appear.

Note: If " " does not appear, remove the unused strip and repeat step 5.
- Pull back the sliding barrel till it clicks, and the lancing device is ready to use.
- Hold the lancing device firmly against sampling site.
 - Press the release button.



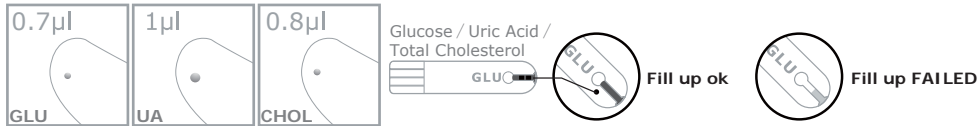
- Wipe off the first drop of blood.
- Massage your finger gently till a round drop of blood forms.



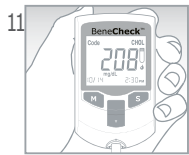
- Touch the blood sample with strip inlet.
- The sample will be drawn automatically.

Note:

Make sure you have enough sample for sufficient test.
If the blood smears, please wipe off and squeeze another drop of blood.



Note: Insufficient fill up of blood sample could lead to inaccurate or failed test result.



- After count down, the result will display on the screen.
- Then eject the used strip into a biohazard waste container.
- The meter will turn off automatically.

Note:

- Please code your meter when you first use or open a new vial of strips. If you have any question, please read Chapter 2.3.
- Please follow the instruction while testing. Improper operation may result in inaccurate test result or damage the system.
- Please finish the test within 5 minutes or the meter will turn off automatically.
- The meter will not turn on if you insert the wrong end or wrong side of strip.
- Do not use expired strip.



Warning :

- Lancets cannot be reused.
- Please always use certified lancets to ensure safety.

3.3 Alternate Site Testing (AST)

The meter allows you to test glucose from your fingertip, palm or forearm. Blood obtained from palm and forearm may reduce pain during sampling process, but the glucose level changes faster in palm and forearm. These differences may cause wrong medical decision.

Note: Please consult healthcare professional before AST sampling.

Suitable timing to acquire blood sample from alternate sites:

- Routinely before meal
- Prior to or two hours after a meal/a short-acting or rapid-acting insulin analogue/exercise.

DO NOT test from alternate sites:

- During or less than two hours after eating, exercising, or taking medication.
- When you are ill.
- If you think your glucose level is low or you are unaware of your low blood glucose condition.
- If you are examined for hypoglycemia or hyperglycemia.
- Within two hours after a short-acting or rapid-acting insulin analogues.
- Your AST test result do not match your health condition.
- You are operating machinery or driving a car.

Note:

- Repeat sampling from fingertip if your AST test result do not match your health condition.
- Repeat puncturing the same spot may cause soreness and calluses.
- If it is difficult to sample from alternative site, please sample from fingertip instead.

Palm sampling

Choose an area below your thumb or pinky finger, with no visible veins and away from deep palm print.



Forearm sampling

Choose an area away from bone, visible veins and hair. Please massage or warm the site to increase blood flow in order to get sufficient amount of blood sample.

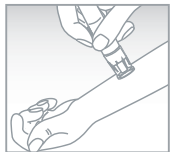
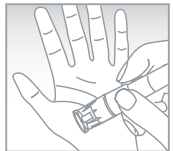


Lancing and sampling from an alternative site:

- 1.Repeat the steps1-7 in Chapter 3.2.
(Replace the lancing device tip with adjustable AST tip.)
- 2.Then press and hold the lancing device against your palm or forearm for a few seconds, then press the release button.
- 3.Keep holding the sampling device and tip against your skin.Maintain pressure until sufficient blood sample formed.
- 4.Carefully lift the lancing device away. Do not smear the blood sample.
- 5.Then repeat the steps 10 and 11 in Chapter 3.2.

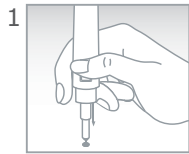
Note:

- It may need to wait a little longer to get sufficient amount of blood sample from the palm or forearm. Do not squeeze the site excessively.
- If the blood sample runs or spreads, do not use the sample. Try puncturing again in a smoother area.
- If you still fail to get enough blood samples at the deepest setting of lancing device, please try to get lancets in lower gauge.



3.4 Care after Testing

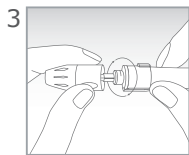
1. Please follow the instruction to discard used lancets into an appropriate biohazard container.



- Do not touch the used lancet, and pierce it into the protective lancet cover.



- Discard the used lancet into biohazard waste container.



- Recap the lancing device and storage.

2. Record your test result.

3. Store your meter, strips and other items in a cool and dry environment.
(Please check the specification in Chapter 8.)

Special Message

Test Mode	Lo	Hi
Glucose	< 20 mg/dL (1.10 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)

Note:

- Please check your meter performance regularly.
- 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.
- Choking hazard – keep away from children.



Warning :

- Do not disassemble the meter for any reason.
- Do not modify this equipment without authorization of the manufacturer.
- 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.

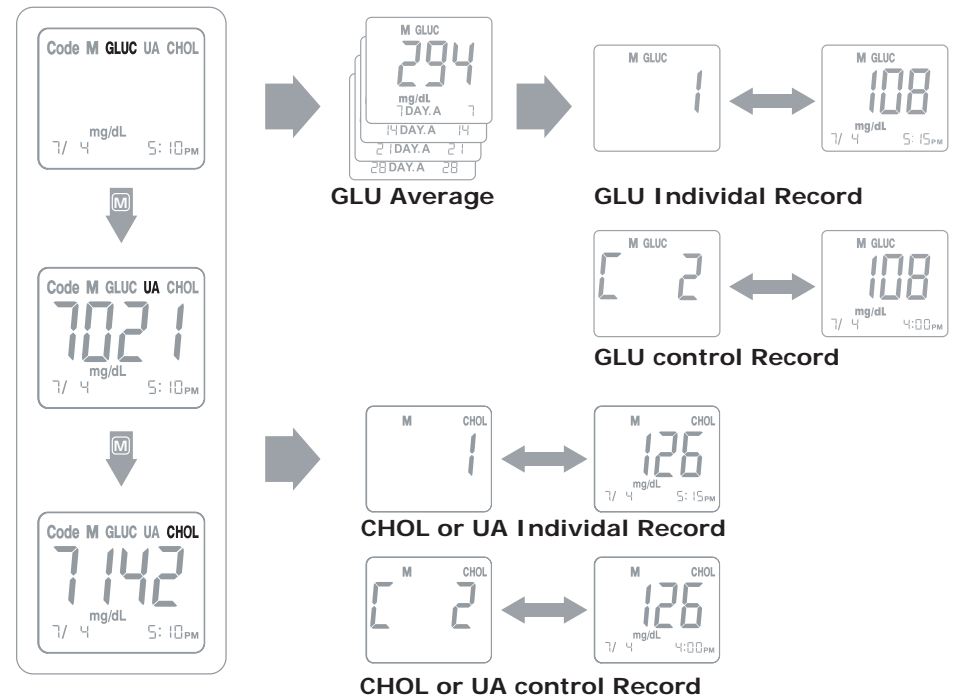
Chapter 4 Meter Memory Function

The meter can record 360 results of glucose, 50 results of total cholesterol, and 50 results of uric acid (include test results and control solution test results). It can also count 7-,14-,21- and 28-days average for glucose. The latest test result will replace the oldest when the records exceed maximum memory capacity. The memories start record from M1 to M360 or M1 to M50.

Directions for Checking Memories:

- 1.No test strip in the meter.
- 2.Press "M" button for 3 seconds till a short "beep" to enter the memory mode.
- 3.After a full display on screen, press "M" button to switch between GLUC, UA, and CHOL mode. Press "S" button to select.
- 4.In GLU memory mode, it will display 7-, 14-, 21-, 28-days average first then individual record. CHOL and UA memory mode will show individual record directly. Press "S" button for next test record, and press "M" button for previous record.
- 5.Once you enter one memory mode, you cannot switch. Press "M" button for 3 seconds or wait for the meter to turn off. Then repeat step 1-3 to select another test mode.

Note:The control results are not included in the average.



Chapter 5 Control Solution Test

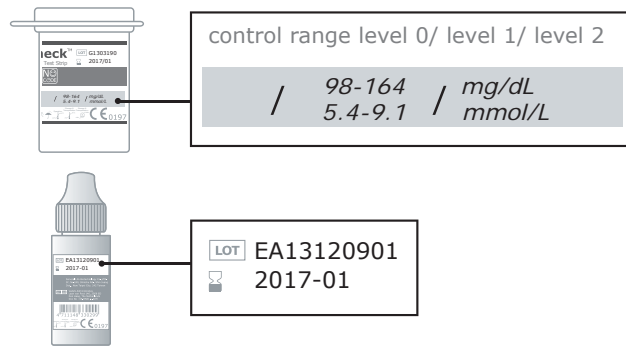
Control solution is used to check the performance of the kit. The meter performs adequately when control test falls within the range listed on test strip vial label.

The meter kit should be checked:

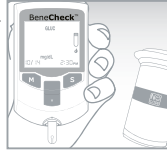

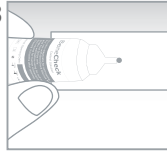


- When the meter and strip do not work properly.
- When the test result is unusual or inconsistent.

Control solution range is shown as follow:

Please check your strip vial label for exact range.

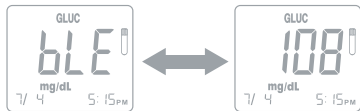


Directions:

- 
 - Insert an unused strip into the meter.
 - 
 - Press "M" button for 3 seconds to enter the control solution mode.
 - 
 - Shake well and discard the first three drops of control solution. And put one drop onto a clean surface.
 - 
 - Touch the control solution with strip sample inlet.
 - 
 - The result will display after countdown.
 - Compare the result with the range listed on test strip vial.
- Note:**
- Do not reuse the test strip.
 - Newly opened vial of control solution and test strips must be marked with the opening date.
 - Close the strip vial lid completely after use.
 - Do not use the meter if the control range do not fall in the correct range.
 - If the control test keeps result wrongly, please contact an authorized distributor for help and service.
 - Control solutions are not included. Please contact an authorized distributor for checking the meter kit performance.

Chapter 6 Transmission Function

The meter provides Bluetooth transmission function. It can transmit test results to connected device wirelessly via Bluetooth.



The screen show "bLE" means Bluetooth transmission function is working.

- The meter with Bluetooth 4.0 can apply to IOS, Android 2.3.3 and above.
- The meter complies with IEC 60601-1-2 and the relevant EMC (electromagnetic compatibility) and RF (radio transmission) requirements regulated by US Federal Communications Commission. The purpose of these requirements is to ensure that meter does not affect or being affected by other devices during operation.
- The meter and the transmission function may be interfered while other device is operating nearby. Ex: mobile phone, wireless internet, etc.
- If the transmission has been interfered. Please keep the meter away from the source of interference or turn off the interfering device.
- Please make sure the meter and the receiving device are placed within a reasonable distance (less than five meters) during transmission via Bluetooth.
- Please do not share the meter with other people if you are using Bluetooth transmission function. The test results from other people will also transmit to the receiving device, and it will influence your test record.
- The Bluetooth transmission function may not work on certain types of mobile phone due to the compatibility of Android systems.

Chapter 7 Care and Maintenance

7.1 Storing Your Meter

The meter will be affected by improper storage and handling. Please follow the instructions and check Chapter 8 for specifications.

- Please avoid bump or other violent behavior, it may caused damage to the meter.
- Do not use this meter in a very dry environment, especially if synthetic materials are present. It may cause damaging static discharges in a dry environment.
- Do not use the meter near the source of electromagnetic radiation, ex: electrical or electronically equipment. It may interfere meter operation.
- Do not storage the strips in high humidity environment, or expose directly to the sunlight.
- Do not freeze or refrigerate the meter and strips.
- Keep the meter clean by wiping the exterior appearance with tissues or lin-free cloth.
- Keep your hand dry and clean while handing the strips and performing the test.
- Do not disassemble the meter for any reason.

7.2 Cleaning and Caring for Your Meter






Gently wipe the meter surface with a soft cloth slightly damp with one of the following cleaning solutions:




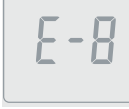


- 75% alcohol.
- Super Sani-Cloth disposable wipes.
- Mild dishwashing liquid with water.
- 10% household bleach solution made in the same day. (1 part bleach with 9 part water)

Note:

- Do not allow any wet cloth or liquid to clean your meter.
- Do not allow any liquid run in or around the test port and battery cover.
- Make sure the meter is completely dry before use.

Chapter 8 Error Message and Trouble Shooting

Message	Cause	Solution
	<ul style="list-style-type: none"> • Problem with code strip. • Insert the strip in an improper way. • Problem with test strip. 	Repeat the coding procedure and ensure the code number is the same in label, code strip and screen. Insert the strip again. If the problem persists, please contact the distributor for service.
	<ul style="list-style-type: none"> • The power of the battery is too low to run a test. 	Replace a new battery immediately.
	<ul style="list-style-type: none"> • Problem with code strip. • Insert the code strip in an improper way. 	Repeat the coding procedure and ensure the code number is the same in label, code strip and screen. If the problem persists, please contact the distributor for service.
	<ul style="list-style-type: none"> • The temperature was below or above the meter operating range. 	Repeat the test after the meter has reached to the temperature within the operating range. If the problem persists, please contact the distributor for service.
	<ul style="list-style-type: none"> • An used test strip or a damp strip. 	Review the instructions and try again with a new test strip. If the problem persists, please contact the distributor for service.

	<ul style="list-style-type: none"> • Uncompleted test caused by removing the test strip during the measurement. 	Review the instructions and try again with a new test strip. Please don't remove the strip before the test is completed.
	<ul style="list-style-type: none"> • Problem with strip. 	Review the instructions and try again with the same test strip. If the problem persists, please contact the distributor for service.
	<ul style="list-style-type: none"> • Use an improper code strip. 	Repeat the coding procedure and ensure the code number is the same in label, code strip and screen. If the problem persists, please contact the distributor for service.
	<ul style="list-style-type: none"> • Do not get enough sample volume for the test. 	Take a new strip and make sure you have enough sample volume for your test. Repeat the test again. If the problem persists, please contact the distributor for service.
	<ul style="list-style-type: none"> • Test result is higher than the range listed on Chapter 9. 	<ol style="list-style-type: none"> 1. Review the instructions and try again with a new test strip. 2. If the problem persists, please call local authorized distributor for help.
	<ul style="list-style-type: none"> • Test result is lower than the range listed on Chapter 9. 	<ol style="list-style-type: none"> 1. Review the instructions and try again with a new test strip. 2. If the problem persists, please call local authorized distributor for help.

Chapter 9 **Specification**

Test Sample	Fresh Capillary Whole Blood
Measuring Time	GLU:5 seconds; CHOL: 26 seconds; UA: 15 seconds
Measuring Range	GLU: 20-600 mg/dL (1.1 - 33.3 mmol/L); CHOL: 100 - 400 mg/dL (2.59 - 10.35 mmol/L); UA :3 - 20 mg/dL (0.18 - 1.19 mmol/L)
Sample Volume	GLU: 0.7 µL; CHOL: 0.8 µL; UA: 1 µL
Storage & Transportation Condition	4 - 30°C (39-86°F)
Operation Temperature	10 - 40°C (50-104°F)
Storage & Transportation Relative Humidity	10-90%
Memory	460 Test Results (GLU: 360 ; CHOL: 50 ; UA: 50)
Battery Type	One 3V (CR2032) lithium battery
Battery Life	Approximately 1,000 tests
Dimensions	88*52*16 mm
Weight	About 50g (with battery)
Altitude	10,000 feet (3048 m)
Expected Service Life	5 years
Transmission Function	Bluetooth 4.0

Note:

- Please refer to the strip insert for accuracy, precision, limitation, and other important information.

Electromagnetic Compatibility

This meter meets the electrostatic discharge immunity testing was basic standard IEC6100-4-2. In addition, the meter meets the electromagnetic emissions requirements as per EN61326. The purpose of these requirements is to ensure that meter does not affect or being affected by other devices during operation.



Warning :

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. The BeneCheck Multi-Monitoring Meter may provide a description or list of equipment with which the BeneCheck Multi-Monitoring Meter has been tested in a stacked or adjacent configuration.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BeneCheck Multi-Monitoring Meter, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

FCC Statement:

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.