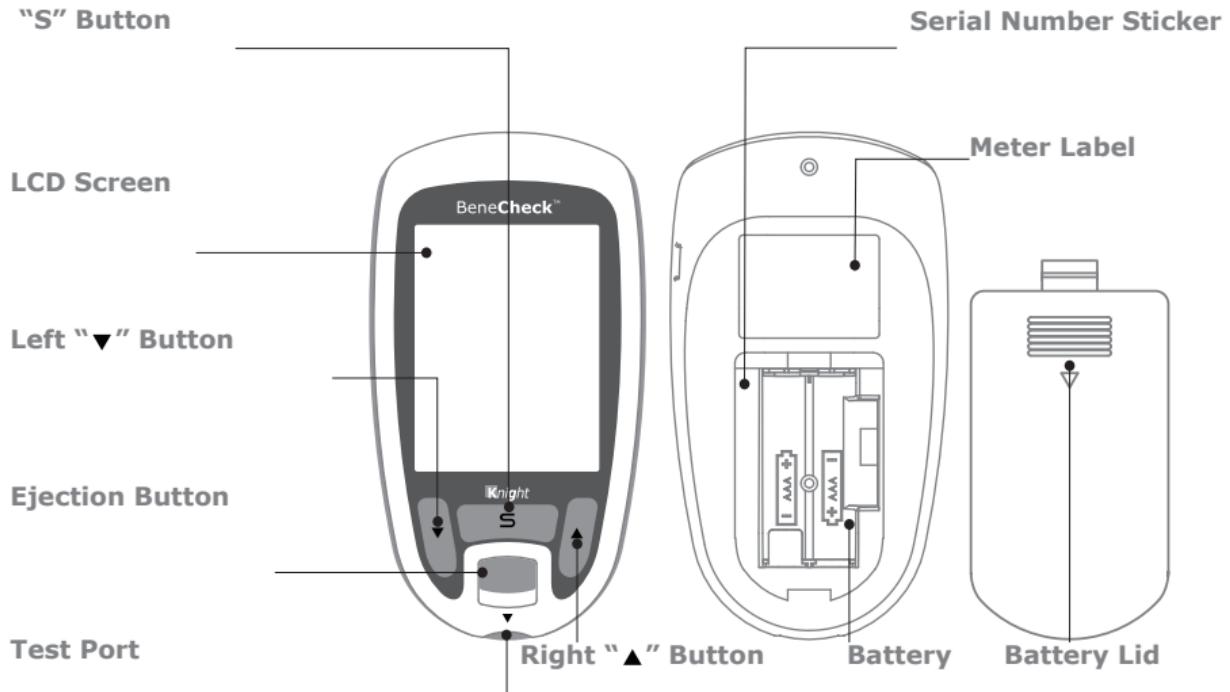
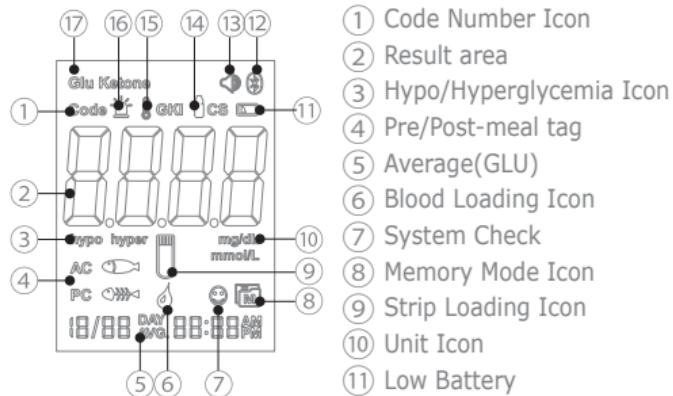


BeneCheck Meter Kit Meter (Front Side & Back Side)



LCD Screen Display: Information and test result display



- ① Code Number Icon
- ② Result area
- ③ Hypo/Hyperglycemia Icon
- ④ Pre/Post-meal tag
- ⑤ Average(GLU)
- ⑥ Blood Loading Icon
- ⑦ System Check
- ⑧ Memory Mode Icon
- ⑨ Strip Loading Icon
- ⑩ Unit Icon
- ⑪ Low Battery
- ⑫ Bluetooth on
- ⑬ Beeper Icon
- ⑭ Control Solution
- ⑮ Temperature Icon
- ⑯ Alarm Icon
- ⑰ Test Mode Icon

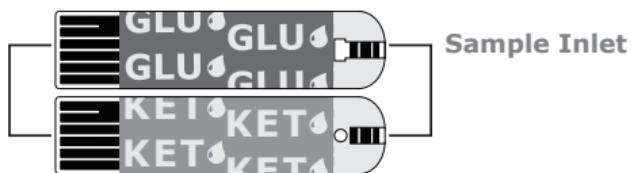
Alert Tones:

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

Test Strip :

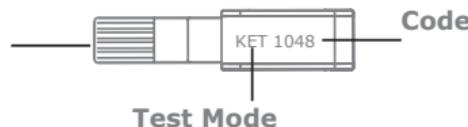
GLU (GDH-FAD)- Glucose KET - Ketone

Electronic Contact Bars



Code Strip :

Contact Bar



Labelling and Information



- Use-by date



- Manufacturer



- Do not re-use



- Keep dry



- Consult instructions for use



- *In-vitro* diagnostic medical device



- Batch code



- Date of Manufacture



- Serial number



- CE certification



- Keep away from sunlight



- Caution, consult accompanying documents



- Comply with WEEE Directive 2012/19/EU



- Use within 3/6 months after first opening



- Catalogue number



- Temperature limitation



- Authorized representative in the European Community



- Humidity limitation

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Chapter 1 Introduction

Introduction

Please read carefully before using meter kit, and consult healthcare professional before making any important medical decision. Please contact your local customer service for further assistance with the product.

Normal Environmental Conditions

This meter designed under the following conditions:

- Indoor use
- Overvoltage category II
- Pollution degree 2

Electromagnetic Compatibility

This meter meets the electromagnetic compatibility, emission, and immunity, and the requirements of IEC 61326-2-6.

Intended Use

BeneCheck Knight Blood Glucose & β -Ketone Monitoring System is only for *in vitro* diagnostic use which is used for quantitative measurement of blood glucose or β -Ketone level in fresh capillary whole blood as aid in monitoring diabetes management at home or in clinical settings. Alternative site for glucose testing is allowed (fingertip, palm & forearm).

Fresh venous or artery whole blood drawn by healthcare professionals can be used only for testing blood glucose, not for the diagnosis.

Principles of the Examination Method

- Electrochemical Biosensor.

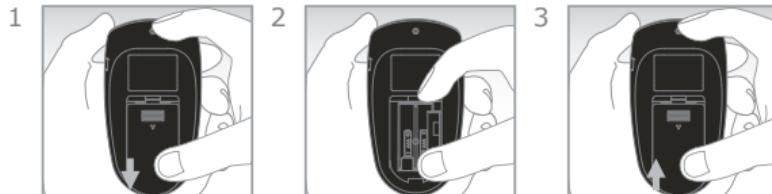
The meter is plasma-calibrated by reference instruments, which are traceable to the following standard reference materials and methods.

Test	Standard	Method
Glucose	NIST SRM 917	Glucose Dehydrogenase
β -Ketone	internal master calibrator	UV

Chapter 2 Setting the Meter

2.1 Installing/ Replacing the Batteries

This meter uses 1.5V AAA battery * 2. Please remove the plastic tab under the battery before using. **Note:** Dispose the batteries according to your local environmental regulations.



2.2 Setting up the Meter

No Test Strip in the Meter → Press "S" (3 secs) → Enter Setting mode → Turn Off Automatically after Setting

- Setting order: Year/Month/Day/Time Format (12h or 24h)/Hour/Minute/Units/Sound/Hypo/Hyper Alarm
- Press "▲" or "▼" to correct the setting, and press "S" to enter the next setting.

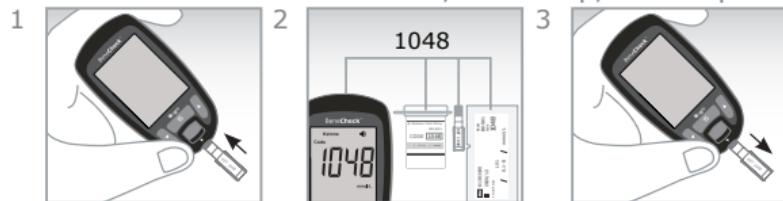
Note: Correct setting is important while managing your health records.





2.3 Code the Meter (β -Ketone)

- Code your meter when you first use it or open a new retail box of strips.
- Make sure the meter is off before you insert the code strip.
- Make sure the code on screen, code strip, and strip vial label or single foil pack are the same.



Note: With Auto Strip Recognition function, once you code your meter, the meter will switch to the test mode automatically when you insert a strip.

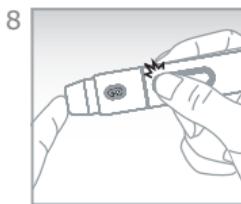
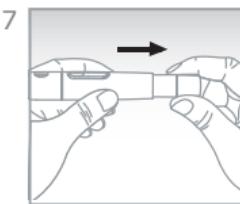
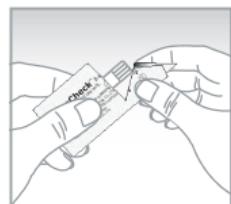
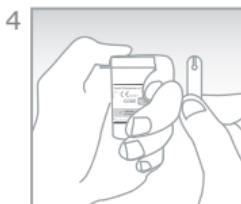
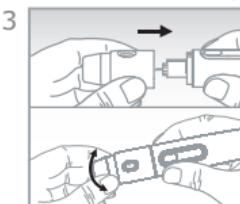
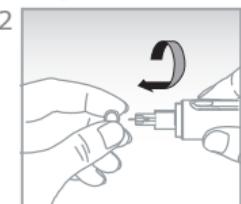
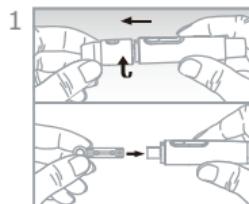
Chapter 3 How to Perform the Test

Materials you need to perform the test:

BeneCheck Meter / BeneCheck Test Strip / Lancing Device / Lancets / Tissue or Cotton Ball with 75% Ethanol or Disinfection Wipes

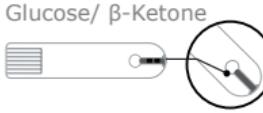
3.1 Perform the Test

- Wash and clean your hands with disinfection wipes, and make sure your hands are dry before testing.
- Please refer to Lancing Device Instructions for detail procedure.





Touch the blood sample with strip.



Fill up ok



Fill up FAILED

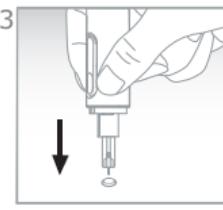
Note: Insufficient fill up of blood sample could lead to inaccurate or failed test result. Do not refill the test strip.



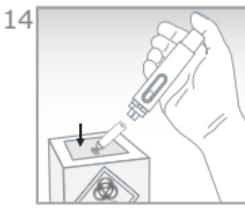
Result will show after countdown. Then eject the used strip to biohazard container.



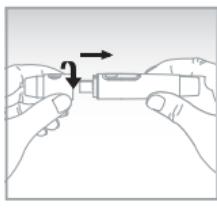
The meter will turn off automatically.



Pierce used lancet into protective cap.



Discard used lancet to biohazard container.



Recap lancet device and storage.

After the blood glucose test result is displayed right after a test, press "▲" or "▼" to select a before-meal flag(AC ) or after-meal flag (PC )

Remove the test strip while the flag has selected, the test result is stored with flag.

3.2 Glucose Ketone Index (GKI)



Insert the ketone test strip.



Make sure the code number is correct.



Press both \blacktriangle and \blacktriangledown for 3 sec. Then enter GKI mode.



Touch the blood sample with strip.



Result will show after countdown. Then eject the used strip to biohazard container.



Insert the glucose test strip.



Touch the blood sample with strip.



Result will show after countdown. Then eject the used strip to biohazard container.



The meter will turn off automatically.

Note:

- Please finish the test within 3 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.
- Marked open date on new open strip vial, do not use expired strip.
- Dropping, bumping or other violent impact will damage the meter or cause malfunction.
- Do not use the meter in an environment with possible magnetic, electromagnetic, and radioactive interferences.
- Do not inhale or swallow.
- Education level at least 15 years old and 8 years intensive reading experience (school), no maximum.

**Warning:**

- Please follow local regulations to discard used test strips and lancets.
- Used test strips, lancets and any other material that has been in contact with blood should be treated as potential biohazards.
- If user has infectious disease, the used test materials could be sources of infection.
- Lancets cannot be reused.
- Always use certified lancets to ensure safety.
- Keep the system away from children and pets.

3.3 Alternate Site Testing (AST)

You can test your glucose from fingertip, palm or forearm. Taking blood from palm or forearm could reduce the pain, but the glucose level changes faster. 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 or 2 hours after meal/ short-acting or rapid-acting insulin analogue/ exercise.

DO NOT test from alternate sites:

- During or less than 2 hours after meal/ short-acting or rapid-acting insulin analogue/ exercise.
- When you think your glucose level is low or unaware of your low blood glucose condition.
- When you are examined for hypoglycemia or hyperglycemia.
- Your AST test result does not match your health condition.
- When you are ill, or you are operating machinery or driving a car.

Palm sampling

- No visible veins.
- Away from deep palm prints.



Forearm sampling

- Away from bones, visible veins and hair.



Sampling from an Alternative Site:

1. Repeat the steps 1-7 in Chapter 3.1.(Replace the lancing device tip with adjustable AST tip.)
2. Hold the lancing device against sampling site, and press the release button.
Keep holding the lancing device against sampling site until sufficient sample formed.
3. Then repeat steps 10-15 in Chapter 3.1.

Note:

- Sampling from fingertip if your AST test result does not match your health condition.
- Repeat puncturing the same spot may cause soreness and calluses.
- Do not squeeze the site excessively. It may take longer for sufficient blood sample to form.
- Do not use smeared blood sample, please acquire new blood sample.
- If you continue failing in getting enough blood samples, please try to get lancets in lower gauge or sample from fingertip instead.

Chapter 4 Meter Memory Function

- Glucose - 800 results, capable in counting 7-, 14-, 30-, 60- and 90-day average
- Ketone - 200 results
- GKI - 200 results

The latest test result will replace the oldest when the records exceed maximum memory capacity. The memories start record from 1 to 800 or 1 to 200, include test results and control solution test results.

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

Directions for Checking Memories:

No test strip in the meter → Press “▼” (3 secs) → Enter memory mode → Press “▼” or “▲” to switch mode (Glu/ Ketone/ GKI) → Press “S” to confirm → Press “▲” or “▼” to view each test record → Press “S” (3 secs) to turn off

- In Glu memory mode, Press “S” will display 7-, 14-, 30-, 60- and 90-day average.
- Once you enter one memory mode, you cannot switch. You need to turn off the meter (Press “S” for 3 seconds) and enter the memory mode again.

Memory Records are shown as follows:



Test Record



7-, 14-, 30-, 60-
and 90-day average



Control Record



Chapter 5 Control Solution Test

Control solution is used to check the performance of the kit.

The meter kit should be check:

- 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 or single foil pack for exact range.



Perform a Control Test:

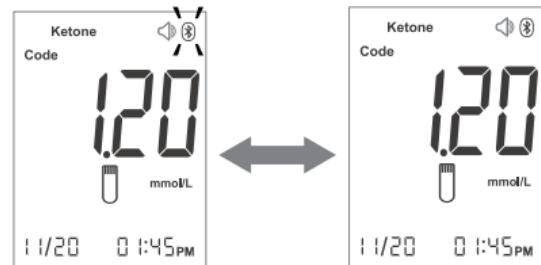
Insert an unused strip → Make sure the code number is correct (Ketone) → Press "S" (3 secs) → Enter control solution mode (shown CS on screen) → Shake the control solution well → Discard first three drops → Put one drop onto a clean surface → Touch the control solution with strip sample inlet → Test result display after count down → Compare the result with the control range on test strip vial or single foil pack

Note:

- Do not reuse the test strip.
- Marked open date on new open control solution.
- Do not use the meter if the control test is out of range.
- If the control test keeps result wrongly, please contact an authorized distributor.
- Control solutions are not included. Please contact an authorized distributor for purchasing.

Chapter 6 Transmission Function for BC010D

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



The screen show "Bluetooth" 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 61326-2-6 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.
- Frequency range: 2402 - 2480MHz. Maximum RF power: 6 dBm.

Chapter 7 Care and Maintenance

7.1 Storing Your Meter and Strip

Meter:

- Avoid bump or violent behavior.
- Do not use in extremely dry environment. It may cause static discharges.
- Do not use under electromagnetic radiation, ex: electrical equipment.
- Do not disassemble the meter for any reason.
- Keep meter clean by wiping the exterior appearance with tissues or lint-free cloth.
- No modification of this equipment is allowed.
- Do not expose the meter under lint, dust, sunlight, heat or humid environment.

Strip:

- Do not store in high humidity environment, or expose directly to sunlight.
- Do not freeze or refrigerate the meter and strips.
- Keep your hand dry and clean while handing the strips and performing the test.
- Do not bend, cut or fold the strips.

7.2 Cleaning and Caring for Your Meter

Please use soft cloth slightly damp with one of the following solution to clean meter surface after finish the test.

- 75% alcohol
- Super Sani-Cloth disposable wipes
- Mild dishwashing liquid with water
- 10% household bleach solution and 90% water

Note:

- Do not allow any other wet cloth or liquid.
- Do not allow any liquid run in or around the test port and battery cover.
- Make sure the meter is completely dry before use.
- Protection impairment if used in a manner not specified by the manufacturer.

Message	Cause	Solution
	<ul style="list-style-type: none">• Problem with code strip.• Problem with test strip.• Insert strip improperly.	Repeat the coding procedure (Chapter 2.3) and insert the strip again. If the problem persists, please contact local distributor for service.
	<ul style="list-style-type: none">• Low battery.	Replace with new battery.
	<ul style="list-style-type: none">• Problem with code strip or meter.• Insert code strip improperly.	Repeat the coding procedure (Chapter 2.3). If the problem persists, please contact local distributor for service.
	<ul style="list-style-type: none">• Incorrect meter operating temperature.	Repeat the test after meter return to operating temperature. If the problem persists, please contact local distributor for service.
	<ul style="list-style-type: none">• Used strip.• Damped strip.	Follow Chapter 3.1 and repeat the test with a new strip. If the problem persists, please contact local distributor for service.

E-9

- Test incomplete due to removing the strip during measuring.

Follow Chapter 3.1 and repeat the test with a new strip. Do not remove the strip before the test is completed.

E-1

- Improper code strip.

Repeat the coding procedure (Chapter 2.3). If the problem persists, please contact local distributor for service.

E-8

- Sample volume not enough.

Repeat the test with a new strip, and make sure the sample volume is enough. If the problem persists, please contact local distributor for service.

Hi

- Test result is higher than the range listed on Chapter 9.

Follow Chapter 3.1 and repeat the test with a new strip. If the problem persists, please contact local distributor for service.

Lo

- Test result is lower than the range listed on Chapter 9.

Follow Chapter 3.1 and repeat the test with a new strip. If the problem persists, please contact local distributor for service.

Chapter 9 Specification

Test Sample	GLU: Fresh Capillary Whole Blood from fingertip, palm, or forearm/ venous blood/ arterial blood KET: Fresh Capillary Whole Blood from fingertip
Measuring Time	GLU:5 seconds; KET: 10 seconds
Measuring Range	GLU:20-600 mg/dL (1.1-33.3 mmol/L); KET: 0.1-8 mmol/L
Sample Volume	GLU: 0.7 μ L; KET: 1 μ L
Storage & Transportation Condition	Meter :0-60 $^{\circ}$ C(32-140 $^{\circ}$ F) Strip :4-30 $^{\circ}$ C(39-86 $^{\circ}$ F)
Operation Temperature	GLU:10 - 40 $^{\circ}$ C (50-104 $^{\circ}$ F) KET:15 - 40 $^{\circ}$ C(59-104 $^{\circ}$ F)
Storage & Transportation Relative Humidity	10-90%
Open Vial Relative Humidity	10-90%
Memory	1200 Test Results (GLU: 800 ; KET: 200 ; GKI: 200)
Battery Type	1.5V AAA battery * 2
Battery Life	Approximately 1,000 tests
Dimensions	123*67*33mm
Weight	104g (with battery)
Altitude	10,000 feet (3048 m) (700~1013 hpa)
Expected Service Life	5 years (Approximately 10,000 times)
Transmission Function	Bluetooth 4.0 for BC010D

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

Chapter 10 Federal Communications Commission (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.

You are cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.

This device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Contents of the Kit (please check the meter outer box for exact detail)

- BeneCheck Knight Blood Glucose & β -Ketone Monitoring Meter (BC0100、BC010D)
(with 1.5V AAA battery * 2)
- User's Manual
- Quick Guide
- Carry bag

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

- BeneCheck Supreme Glucose Test Strip (BK-SG1) (with Insert)
- BeneCheck β -Ketone Test Strip (BK-SK1) (with Code strip & Insert)
- BeneCheck III Glucose Control Solution
- BeneCheck β -Ketone Control Solution

Note: After purchasing, if the contents are damaged, please contact authorized distributor immediately.