

**eBketone**

Blood Ketone Monitoring System



## User's Manual

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# Welcome

Thank you for selecting the eBketone blood ketone monitoring system.

## Read This First:

### [Important]

Read these instructions for use and the User's Manual supplied with your meter before you monitor your blood  $\beta$ -ketone. Failure to follow instructions will cause incorrect results.

### [Intended use]

The eBketone blood ketone monitoring system is indicated for home (lay user) or professional use in the management of patient who might concern about ketone levels. It is for self-testing or healthcare professional use outside the body whether you would like to have a reference to assess the weight loss program<sup>[1]</sup> or monitor the ketone level to prevent DKA.

It's designed to quantitatively measure blood  $\beta$ -Ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the fingertip. These test strips are for in vitro (use outside the body) diagnostic use only and also for self-testing use. The test results are plasma equivalent. The measuring range of blood  $\beta$ -Ketone concentration in capillary whole blood is from 0.0 to 8.0 mmol/L.

### [Test principle]

When the specimen (blood sample) is applied onto the test strip, the beta-hydroxybutyrate in the blood reacts with the reagent immobilized on the reaction area of the test strip, producing a small electrical current. This current is measured and a result is then displayed on the screen of meter. The intensity of current depends on the amount of beta-hydroxybutyrate in the blood sample.

### [Calibration reference]

The eBketone blood ketone monitoring system is calibrated to reflect plasma beta-hydroxybutyrate using the RANDOX assay kit (RB I 007) by HITACHI 704 Automatic Analyzer.

### [Precision]

The strip performance of precision shows that results typically vary by no more than 6% (Coefficient of variance). Result were obtained in a laboratory study using venous whole blood samples (50 repeats per level).

### [Accuracy (method comparison)]

The strip performance of accuracy shows that results are comparable between trained operators and lay users. The test was assessed at clinics by comparing whole blood beta-hydroxybutyrate results with plasma results obtained using a reference laboratory instrument (HITACHI 704, RANDOX assay kit-RB I 007). This study shows that the eBketone blood ketone monitoring system is well compliant with the laboratory reference method.

### [Terms]

\* Ketogenic diet: The ketogenic diet is a high-fat, adequate-protein, low-carbohydrate diet that in medicine is used primarily to treat difficult-to-control (refractory) epilepsy in children. An elevated level of ketone bodies in the blood, a state known as ketosis, leads to a reduction in the frequency of epileptic seizures.

\* Ketosis: Ketosis is a metabolic state in which some of the body's energy supply comes from ketone bodies in the blood, in contrast to a state of glycolysis in which blood glucose provides energy. Longer-term ketosis may result from fasting or staying on a low carbohydrate diet (ketogenic diet), and deliberately induced ketosis serves as a medical intervention for various conditions, such as intractable epilepsy, and the various types of diabetes.<sup>1</sup>

\*Ketoacidosis: Ketoacidosis is a pathological metabolic state marked by extreme and uncontrolled ketosis. In ketoacidosis, the body fails to adequately regulate ketone production causing such a severe accumulation of keto acids that the pH of the blood is substantially decreased. In extreme cases, ketoacidosis can be fatal.

*There are two major causes of ketoacidosis :*

1. Most commonly, ketoacidosis is diabetic ketoacidosis (DKA) resulting from increased fat metabolism due to a shortage of insulin. It is associated primarily with type I diabetes, and may result in a diabetic coma if left untreated.
2. Alcoholic ketoacidosis (AKA) presents infrequently, but can occur with acute alcohol intoxication, most often following a binge in alcoholics with acute or chronic liver or pancreatic disorders.

Alcoholic ketoacidosis occurs more frequently following methanol or ethylene glycol intoxication than following intoxication with uncontaminated ethanol.

\* Ketogenesis: Most of the Acetyl CoA produced by the oxidation of fatty acids in liver mitochondria undergoes further oxidation in the TCA cycle. Some of them is converted to ketone bodies and this process is known as ketogenesis. The purpose of people who intend to lose weight by exercise and carbohydrate-restrictive plan (ketogenic diet) is to induce a state of fat burning called ketogenesis. When diets are below 65-180 g/day of carbohydrate, glycogen stores begin to be depleted and the shortage of energy source from glucose will be compensated by increase of fat breakdown<sup>[2]</sup>.

# 1. eBketone blood ketone monitoring system

## 1.1. The eBketone system

The eBketone blood ketone monitoring system is intended to monitor blood  $\beta$ -ketone level in fresh capillary whole blood. The system is for in vitro diagnostic use and should only be used outside the body. Also, please do the test only with eBketone test strips.

## 1.2. Equipment in package

Please check the kit package for the eBketone blood ketone monitoring system which includes the following items. If not, please contact the local agents or return to the purchased store.

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### Including items:

Meter Device  
User's Manual  
Lancing Device  
Warranty card

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### Optional items:

Code card  
Lancets  
Ketone Test Strips x 10 pcs/vial  
Battery (AAA) X 2  
Control solution  
Test strip instruction

### 1.3. Product specification

#### eBketone blood ketone monitoring system

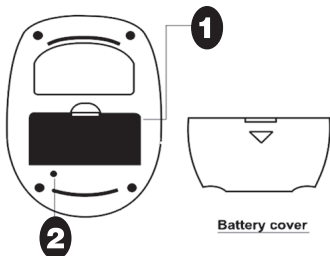
<b>Brand</b>	eBketone
System Model	eB-K01
Specimen	Capillary whole blood
Strip insert from	Top
Acceptable hematocrit range	30-60%
Measuring time	10 seconds
Operating temperature range	10-40(°C)
Relative humidity operating range	<85%
<b>Strip model</b>	LK-01
Enzyme type	beta-Hydroxybutyrate Dehydrogenase(HBDH) Diaphorase (DAD)
Sample volume	0.5μL
Measuring range(mmol/L)	0.0-8.0 mmol/L
Storage condition-Temperature	4-30(°C)
<b>Meter model</b>	eB-K01
Memory capacity	180 with time and date
Unit display	mmol/L
Time display	24Hrs
Storage condition-Temperature	0-50(°C)
Storage condition- Relative humidity	<95%
Dimension	87x63x23(mm)
Weight	≤80(g)
Power supply	AAA x 2

## 2. About eBketone blood ketone monitoring system



The front side of the test meter

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

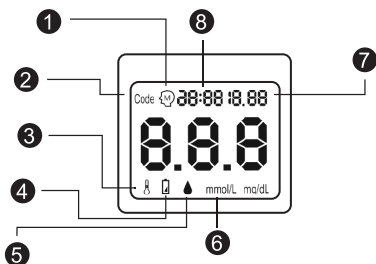


1. Battery Slots:  
Put in two AAA batteries.
2. Clock setting knob:  
Press to set up time and date.

The back side of the test meter



## Screen description



1. Memory symbol

2. Code symbol

3. Thermograph

4. Battery sign

5. Blood drop sign

6. Measuring unit

7. Date

8. Time

## The test strip

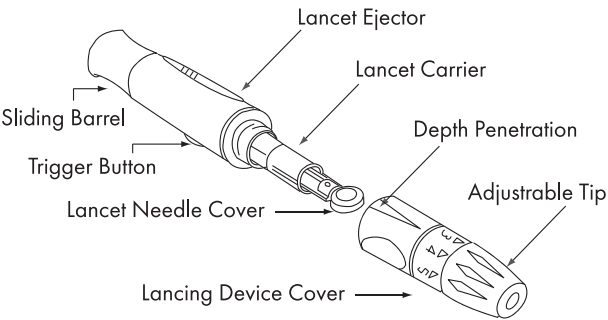


1. Top edge: Apply a capillary whole blood sample to here.

2. Meter connect edge: Insert this side to meter.

3. Indication: To make sure if blood has been applied enough to fill the reaction area.

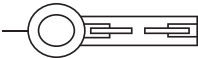
# The lancing set



Lancing device

## Lancet

Circular protective cover



## 3. Operating methods

### 3.1. Before testing

#### 3.1.1. Installing the batteries

eBketone testing meter requires two 1.5 volt (AAA) alkaline batteries.

Step 1: Open the battery cover.

Step 2: Follow the direction sign to put in the battery.

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

Step 4: Follow section 3.1.2 to setup the time and date.

Step 5: Place the battery cover back.

Note: If the testing frequency is low, please remove the batteries from battery socket, in case of leaking and causing damage to the meter.



Use the correct battery for this product.

#### 3.1.2. Setting mode

You may set up the time and date in the setting mode, which may appear under the following scenarios: 1) installing the batteries for the first time, 2) changing the batteries, and 3) pressing the clock setting knob.

Step 1: Open the battery cover and find the clock setting knob on the left bottom side.

Step 2: Press and release the clock setting knob, the year digits will start to flash on the screen.

Step 3: Press and release the button on the front side of the meter to adjust the digits until the correct year is shown on the screen. (Only last two digits of year are shown on the screen, for example: 2017)

- Step 4: Press and release the clock setting knob, the month digits start flashing on the screen.
- Step 5: Press and release the button on the front side of the meter to adjust the digits until the correct month is shown on the screen.
- Step 6: Press and release the clock setting knob, the day digits will start to flash on the screen.
- Step 7: Press and release the button on the front side of the meter to adjust the digits until the correct day is shown on the screen.
- Step 8: Press and release the clock setting knob, the hour digits will start to flash on the screen.
- Step 9: Press and release the button on the front side of the meter to adjust the digits until the correct hour is shown on the screen.
- Step 10: Press and release the clock setting knob, the minute digits will start to flash on the screen.
- Step 11: Press and release the clock setting knob, the "OFF" appears on the screen to exit the time and date setting mode.

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

### 3.1.3.Coding the meter

For accurate results, your meter should be calibrated with the code card every time when you open a new vial of test strips. After you calibrate the meter with code card, you can start testing your blood ketone.

- Step 1: Open a new box of eBketone blood ketone test strip and take out the code card from box.
- Step 2: Insert the code card into the test slot.
- Step 3: You should hear a "beep" sound and a code number will appear on the screen.
- Step 4: Check the code number on the screen with the number on the vial of test strips. These two numbers should be the same, if not please stop testing and contact your local agent.
- Step 5: Remove the code card and you are ready for blood ketone testing.

### **3.2. Start testing**

- Step 1: Remove the cap from the lancing device.
- Step 2: Insert a lancet into the lancing holder and push it down until it is fully seated.
- Step 3: Twist the circular protective cover in the front of the lancet. Then, remove the protective cover from the lancet.
- Step 4: Put the cap back onto the lancing device.
- Step 5: You have to adjust the depth setting of lancing device before using. There are 5 levels of depth you can choose. Level 1 is the shallowest one. Level 5 is the deepest one.
- Step 6: Choose a desired skin penetration depth for yourself by rotating the depth selector until the depth selection window displays your desired depth setting.
- Step 7: Slide the ejection/cocking control back until it is triggered.
- Step 8: Wash your hands with warm, soapy water. Rinse and dry thoroughly.
- Step 9: Open a new vial of test strips. Take out a test strip from the vial and close the cap properly.

- Step 10: Follow the arrow direction to insert the test strip into test slot.  
The meter will turn on automatically when you insert the test strip properly.  
Insert the strip into the test slot. "CH-" will be shown on the screen and the meter will self-detection. If the self-detection fails, "E01" will appear on the screen. If the meter is normal, the code of the code card will be shown on the screen.
- Step 11: Then, the code number will be shown on the screen with a "beep" sound. Please confirm this code number with the "code number" on the label of vial are the same.
- Step 12: Put your hands on a table and press the lancing device against your fingertip.
- Step 13: Push the trigger on the lancing device and the lancet will prick a hole onto your finger.
- Step 14: To obtain a drop of blood, squeeze your finger gently to form a small drop of blood.
- Step 15: Then, confirm the blood drop sign flashed on the screen until you apply the blood sample to the strip.
- Step 16: The blood will be drawn into the strip automatically. You can confirm the blood is enough or not by observing the indication slot. If the blood is not enough to fulfill the reaction well, the result may be incorrect. Please repeat the test again.
- Step 17: Hold your blood to the strip until after you hear the "beep" sound from the meter.
- Step 18: The meter starts to count down from 10 seconds.
- Step 19: After counting down from 10 to 1, your testing result will be shown on the screen and it'll be stored automatically in the meter's memory.
- Step 20: The meter will turn off automatically when you remove the test strip.

Step 21: Dispose the used strip in a sealed container.

Step 22: Remove the cap from the lancing device and put the protective cover back onto the lancet.

Step 23: Push the ejector forward and dispose the lancet to a sealed container.

### 3.3. Using the meter memory

Your blood ketone testing meter stores 180 most recent ketone testing result with date and time in the memory.

When the memory is full, the latest result is added to the memory and the oldest result is deleted from the memory.

Step 1: You may enter the memory mode by pressing the button on the front side of meter. The "01" will flash followed by the latest ketone results with date and time.

Step 2: Press the button on the front side of meter again to obtain the second record. The result will flash with "02".

Step 3: You may obtain all 180 records by pressing the button on the front side of meter.

Step 4: After the earliest result is shown, the symbol "OFF" will show on the screen, exit the memory mode and meter will shut down automatically.

## 4. A range of expected values

The level of blood  $\beta$ -ketone for healthy people should be less than 0.6mmol/L<sup>[3]</sup>.  $\beta$ -ketone may raise if a person fasts, exercises vigorously or becomes ill for diabetes<sup>[4]</sup>.

\* Please consult your nutritionist or dietician before you start using this product to be a reference of your weight loss program.

\* For diabetic patients, please consult your healthcare professional before you start using this product.

REMEMBER TO REPEAT THE TEST IF THE TEST RESULT FALLS OUTSIDE THE EXPECTED RANGE.

## 5. Checking eBketone blood ketone monitoring system and test strip (Optional)

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

*When to do a control solution test:*

1. When you open a new vial of test strips.
2. Whenever you suspect that the meter or test strips are not working properly.
3. When your blood ketone test results are not consistent with how you feel, or when you think your results may not be accurate.
4. If you drop the meter.

### 5.1. Steps of performing a control solution test

Step 1: Take out a test strip from the vial and fasten the cap properly. Make sure the triangle sign is facing up and insert the electrical contact end of the test strip fully into the test slot. The meter will be turned on automatically and the code number will be shown on the screen. Make sure that this number matches the code number on the vial of test strips.

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



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

Step 4: Touch the drop of control solution to the semicircle shaped cutout on the top of the narrow channel of the test strip. The control solution will be drawn into the strip automatically. The meter will start to count down from 10 seconds.

Step 5: After counting down from 10 to 1, the test result will appear on the screen.

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

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

## 6. Limitation

Blood ketone monitoring system will give accurate results when the following limitations are observed,







- The test strips should not be used for the testing of neonate.
- The test strips are for single use only. DO NOT reuse.
- Handle the meter with care. DO NOT drop the meter on purpose or apply a strong force to the meter.
- DO NOT try to disassemble the meter.
- DO NOT use code card from other test system.
- DO NOT process the test with the meter placed on the hot or cold surface.
- Store the meter in its carrying case.
- Avoid getting dirt, dust, blood sample or liquid in the meter test strip port.





- Clean the outside of the meter using a damp cloth and mild soap. For healthcare professionals, it is acceptable to clean the meter with cleaning solution including 70% ethanol.
- DO NOT remove the test strip while the measurement is in processing.
- DO NOT test with the following specimen:
  1. Hematocrit range out of 30% to 60%
  2. Plasma, serum, venous whole blood specimen.
- DO NOT perform the test if test strip is expired.
- Should perform the test under ambient condition, temperature 10-40(°C) and related humidity <85%.
- Follow the regulations in your area to dispose the used test strips and lancing materials.
- Use universal blood precautions. All patient samples and materials with which they come in contact are considered biohazards and should be handled as if capable of transmitting infection.
- Interference: Please see the table below for the certain concentrations which can affect the function of the meter.

Substance	No interference
Acetaminophen	<1.0 mg/dl
Ascorbic acid	<1.2 mg/dl
Bilirubin	<12.5 mg/dl
Cholesterol	<500 mg/dl
Dopamine	<0.09 mg/dl
L-Dopa	<1.0 mg/dl
Gentisic acid	<1.5 mg/dl
Methyldopa	<0.5 mg/dl
Tolazamide	<2.0 mg/dl
Triglyceride	<2000 mg/dl
Uric acid	<12.5 mg/dl

## 7. Troubleshooting

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

Message	Cause	Action
	The meter is abnormal.	The meter needs to be repaired. Please contact our authorized distributors.
	The test strip is used or damp.	<ol style="list-style-type: none"> <li>1. Please take a new test strip.</li> <li>2. If the error message appears again, contact our authorized distributors.</li> </ol>
	Insert with incorrect brand strip.	Please contact our authorized distributors.
	The battery power is low	It is recommended that you replace the battery at this time.
	When you see this symbol with "Lo", it means the battery must be replaced.	<ol style="list-style-type: none"> <li>1. The meter is not useable. The meter turns off automatically.</li> <li>2. Please replace new battery.</li> </ol>
	The surrounding temperature is too low or too high to perform a test.	Repeat the test in a place between 10°C~40°C (50°F~104°F).

	<p>Temperature is too cold for system to work properly. The meter will be turned off automatically.</p>	<p>Repeat the test in a place between 10°C~40°C (50°F~104°F).</p>
	<p>Temperature is too hot for system to work properly. The meter will be turned off automatically.</p>	<p>Repeat the test in a place between 10°C~40°C (50°F~104°F).</p>
	<p>Blood ketone result may be too high (&gt;8.0mmol/L) to be read by the system. OR There may be a problem with the blood ketone test strip.</p>	<ol style="list-style-type: none"> <li>1. Please test again with a new test strip.</li> <li>2. If the error message appears again, contact your healthcare professional immediately.</li> </ol>
	<p>The code card damaged or using a wrong code card.</p>	<p>Please contact our authorized distributors.</p>















# 8. Reference


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[2] : Wendy PogozelskiJ.; Nicholas Arpaia, and Salvatore Priore. The Metabolic Effects of Low-carbohydrate Diets and Incorporation into a Biochemistry Course. BAMBED, Vol. 33, No. 2, pp. 91-100, 2005.

[3]: Wiggam MI, O’Kane MJ, Harper R, Atkinson AB, Hadden DR, Trimble ER, et al. Treatment of diabetic ketoacidosis using normalization of blood 3-hydroxybutyrate concentration as the endpoint of emergency management. Diabetes Care 1997;20: 1347-52.

[4]: Schade, D.S., Eaton, R.P. Metabolic and clinical significance of ketosis. Special Topics in Endocrinology andMetabolism. 1982;4:1-27.

	Use by date
	Do not re-use
	Keep dry
	Batch number
	Manufacturer
	Paper Recycling
	In vitro diagnostic <i>medical device</i>
	Serial number
	Authorized representative in the European Community/ European Union
	Caution, consult accompanying documents
	Consult instructions for use
	Operating temperature limitation
	Store temperature limitation
	Keep away from sunlight



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


 0123
 This product meets the requirements of Directive 98/79/EC in vitro diagnostic medical devices.



Lancet **CE 0197** and Lancing Device **CE**  
 Beijing Ruicheng Medical Supplies Co., Ltd.  
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