

<b>Client confirmation</b>		Color No.		Description		DESIGN BY: KetoBM		 <b>曁世生物科技</b> <b>VISGENEER INC.</b>			
		<b>Date</b>	<b>Signature</b>		<input type="checkbox"/> K30 <input checked="" type="checkbox"/> K 100	Material: 50P道林  Machining: 十字摺再包摺 摺後尺寸135x35mm	DRAWN BY: KetoBM				INFORMATION CONTAINED ON ALL SHEETS OF THIS PRINT CAN NOT BE REPRODUCED OR USED, IN WHOLE OR IN PART, WITHOUT VISGENEER'S CONSENT. THIS NOTICE DOES NOT IMPLY PUBLICATION.
DWG TITLE: <b>Test strips instruction</b>					UNIT    SCALE    PART NO. <b>MM    1:1    1320756</b>		SHEET    REV. <b>3    Ver.1</b>				
MODEL NAME: <b>KetoBM (EU)</b>					SIZE <b>270x210mm</b>		<b>JUL-2-2021</b>				

## Blood Ketone Test Strips



**IMPORTANT:** Please read this information before using KetoBM Blood Ketone Test Strips

### Intended Use

The KetoBM Ketone Blood Monitoring System is intended for quantitative measurement of  $\beta$ -ketone (beta-hydroxybutyrate) in fresh capillary whole blood from fingertips. The system is intended for *in vitro* diagnostic use and for single patient use. It is to be used as an aid in monitoring a ketogenic diet performed by healthy individuals. It is not to be used for diagnosis or screening of diabetes, nor for use on infants. It is not intended to be used for the diagnosis or treatment of any medical condition. 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 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 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.

### Storing the test strips

- Store test strips at room temperatures between 4-30°C (39-86°F). Do not freeze strips.
- Use test strips at temperatures between 10°C (50°F) and 40°C (104°F) and less than 85% humidity.
- Store test strips in their original vial only; do not transfer them into a new vial or another container.
- Always close the vial lid immediately after use.
- Write the discard date on the vial label when you first open it. Discard remaining strips after 3 months from first opening the vial.



**WARNING:** Keep the test strip vial away from children; the cap is a choking hazard.

### System Measurement Range

The measurement range of the KetoBM Ketone Blood Meter is 0.0 to 8.0 mmol/L.

### Performing the Test:

1. Remove the cap from the lancing device.
2. Insert a lancet into the lancet holder firmly. Twist and remove the protective cover from the lancet.
3. Put the cap back onto the lancing device.
4. Adjust the depth setting on the lancing device. Choose a desired skin penetration depth by rotating the top portion of the adjustable tip until the setting number lines up to the arrow.
5. Slide the ejection control back until it clicks.
6. Wash your hands with warm, soapy water. Rinse and dry thoroughly.
7. Open a new vial of test strips. Remove a test strip from the vial and fasten the cap properly. Make sure the arrow is facing you, pointing down towards the meter and insert the electrical contact end of the test strip fully into the test slot. The meter will turn on automatically.
8. To obtain a drop of blood, press the tip of the lancing device against your fingertip and press the release button. Gently squeeze your finger to form a small drop of blood.
9. Touch the drop of blood to the semicircle-shaped cutout on the top of the narrow channel of the test strip. The blood will be drawn into the strip automatically. Hold your blood to the strip until after the meter beeps. The meter will count down from 10 seconds.
10. After counting down from 10, your test result appears on the screen and is stored automatically in the meter's memory.
11. Record the ketone value in your log book.
12. The meter will turn off once you remove the test strip.
13. Dispose of the used test strip.
14. Remove the cap from the lancing device. Put the protective cover back on the lancet and push the lancet out.
15. Dispose of the used lancet.

### Limitations

- Test strips should not be used for testing on neonates.
- Test strips are single use only. DO NOT REUSE.
- Do not remove the test strip during measurement countdown.
- Use universal blood precautions. All samples and materials with which you come in contact with are considered biohazards and should be handled as if capable of transmitting infection.
- Store your test strips in the following conditions:
  1. Avoid direct sunlight.
  2. Keep away from children.
  3. Store at temperatures between 4°C (39°F) and 30°C (86°F).

Please see below table for 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

### Test Principle

The technology used for the KetoBM ketone blood meter is based on the principle that a small electrical current produced when blood ketone reacts with the reagent immobilized on the reaction area of the test strip and the current charge is proportional to the amount of ketone in the blood.

### Reagent Composition:

- B-Hydroxybutyrate Dehydrogenase (HBDH)(Pseudomonas sp.) 0.5 IU
- DAD (Diaphorase) 0.5 IU
- Mediator 0.015 mg
- Other ingredients 0.02 mg

### Calibration Reference

KetoBM ketone blood meter is calibrated to reflect plasma  $\beta$ -hydroxybutyrate using the RANDOX assay kit (RB1007) by HITACHI 704 Automatic Analyzer.

### Accuracy

The accuracy of KetoBM meter was assessed by comparing readings with the reference values using HITACHI 704 Automatic Analyzer. Ketone concentrations of capillary blood samples were measured using the KetoBM meter. The ketone concentrations of the venous blood samples were analyzed using the HITACHI 704 Automatic Analyzer. The results shown below are from a total of 110 subjects and 3 lots of test strips attending the outpatient clinic.

Number of sample	Slope	Intercept	Correlation Coefficient
110	0.9663	0.0726 mmol/L	0.99

Lay-user KetoBM fingerstick vs HITACHI (ketone range: 0.0-6.5 mmol/L)

< 1.5 mmol/L N=100		Within $\pm$ 0.2 mmol/L		Within $\pm$ 0.3 mmol/L	
Within $\pm$ 0.1 mmol/L	83/100 (83%)	93/100 (93%)	100/100 (100%)		
$\geq$ 1.5 mmol/L N=10		Within $\pm$ 10 %		Within $\pm$ 15 %	
Within $\pm$ 5 %	8/10 (80%)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)

### Precision

Precision was determined using coefficients of variation (CVs) calculated from 50 measurements in the series. To produce 4 different ketone concentrations for 3 lots of strips, venous whole blood samples from healthy volunteers were spiked using different concentrations of ketone solutions.

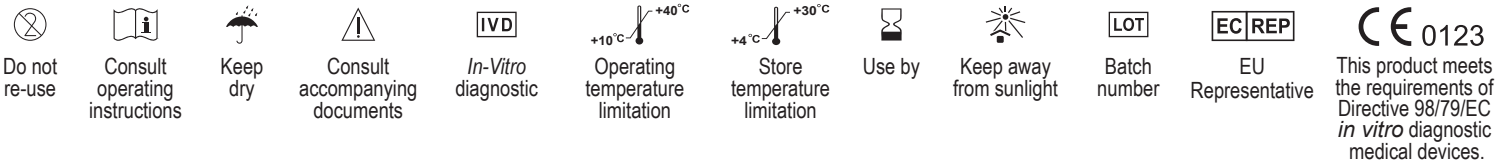
### Repeatability

Ketone levels (mmol/L)	0.6	1.28	2.68	5.6
Average (mmol/L)	0.7	1.4	2.6	5.6
SD (mmol/L)	0.08	0.09	0.10	0.21
C.V. (%)	--	--	4.06	3.86

### Intermediate

Ketone levels (mmol/L)	0.52	2.29
Average (mmol/L)	0.5	2.2
SD (mmol/L)	0.04	0.08
C.V. (%)	--	3.8

## Labeling and Information



## A range of expected values

KetoBM Blood Ketone monitoring system detects levels of  $\beta$ -ketone, which comprises 78% of the ketone bodies present in blood. Expected blood ketone levels for a healthy individual would be less than 0.6 mmol/L.  $\beta$ -ketone levels may rise if an individual fasts, performs vigorous exercise or follows a ketogenic diet.

\*Please consult with your nutritionist or dietician before you start using this product as a reference for your weight loss program.

\*This product is intended to be used solely to track dietary progress and is not intended to diagnose or treat diabetes.

## Checking Blood Ketone Monitoring System and Test Strip (Optional)

KetoBM Control Solution is used to check if the monitoring system (meter working together with test strip) is functioning properly.

### When to do a control solution test:

1. Whenever you suspect that the meter or test strip are not working properly.
2. After dropping the meter.
3. Whenever you question your blood ketone results.

### Steps of performing a control solution test

- Step 1.** Insert test strip into the meter.
- Step 2.** Open a bottle of KetoBM Ketone Control Solution. Storing period for the control solution is 3 months after opening the bottle or up to expiration date listed, whichever comes first.
- Step 3.** Shake the bottle well and squeeze a drop of control solution onto the test strip. Meter will automatically start the countdown from 10 seconds.
- Step 4.** After the countdown, control test result will be shown on the screen. Compare the result with the range printed on the vial to make sure it's within range.

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