


Client confirmation		COLOR NO.	DESCRIPTION	DESIGN BY: KetoBM	 緯世生物科技 VISGENEER INC.														
Date	Signature	<ul style="list-style-type: none"> CMYK 100 85 0 37 CMYK 100 93 28 16 K100 K30 K40 K50 K70 K80 	Cover Material: 180g特鋼 Machining: 亮膜 Content Pages Material: 80g特鋼 Machining: 騎馬釘	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: User manual	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">UNIT</td> <td style="text-align: center;">SCALE</td> <td style="text-align: center;">PART NO.</td> <td style="text-align: center;">SHEET</td> <td style="text-align: center;">REV.</td> </tr> <tr> <td style="text-align: center;">MM</td> <td style="text-align: center;">1:1</td> <td style="text-align: center;">1320755</td> <td style="text-align: center;">20</td> <td style="text-align: center;">Ver.1</td> </tr> </table>					UNIT	SCALE	PART NO.	SHEET	REV.	MM	1:1	1320755	20	Ver.1
UNIT	SCALE			PART NO.	SHEET	REV.													
MM	1:1	1320755	20	Ver.1															
		MODEL NAME: KetoBM (EU)	SIZE 137x90mm		JUL-2-2021														

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For questions or support,
please visit:
KetoBM.com

or email us at
support@ketobm.com

Blood Ketone Monitoring System

Owner's Manual



Video Instructions Available at
ketobm.com/help

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Congratulations on your KetoBM purchase!

Thank you for choosing the KetoBM Blood Ketone Meter. We hope we can be a small part of your ketogenic diet success.

Your new KetoBM Meter uses an advanced autocoding system that does not require code card calibration or control solution. It is designed to provide accurate blood ketone readings at home. Before using the system, please read this user manual and the accompanying Quick Start Guide.

For help interpreting your results, please visit **ketobm.com/results**

For questions or support, please visit our website at www.ketobm.com or email us at support@ketobm.com. We're here to help and want to make sure you have a great experience with your new KetoBM product.

Intended Use

The KetoBM Ketone Blood Meter is intended for quantitative measurement of β -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 β -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 β -ketone concentration in capillary whole blood is from 0.0 to 8.0 mmol/L.

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Important Safety Instructions

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members. Do not use on multiple patients.
- All parts of the kit are considered biohazards and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

Refer to:

"FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

"CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) <http://www.cdc.gov/injectionsafety/Fingertick-DevicesBGM.html>

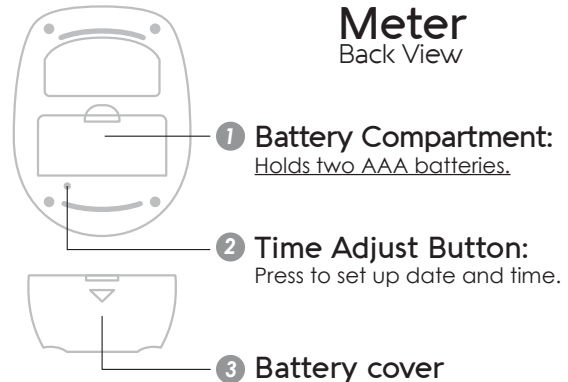
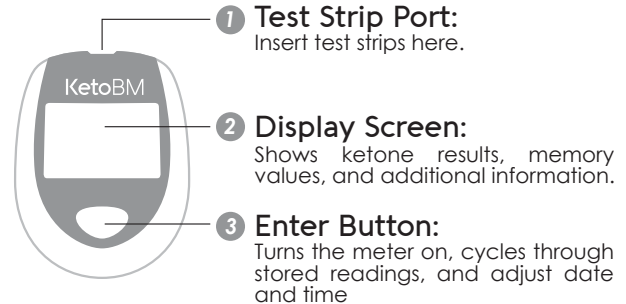
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Safety Instructions and Limitations

- Use this device only for the intended use described in this manual.
- Do not use the device on infants.
- For single patient use only.
- For in vitro diagnostic use only.
- Do not test samples other than fresh capillary whole blood obtained from the fingertip.
- Severe dehydration or excessive water loss may cause inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, and lancets are choking hazards.
- Critically ill patients should not use this device.
- Do not use this device for the diagnosis or treatment of diabetes or any medical condition.
- If you have a health concern or condition, consult a physician.
- Consult a medical doctor before modifying your diet.

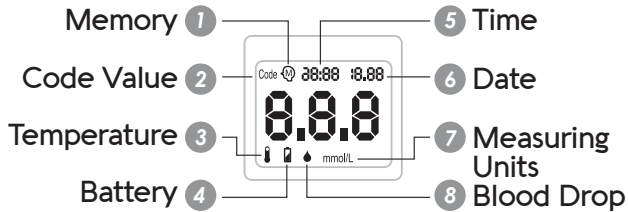
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Meter Front View

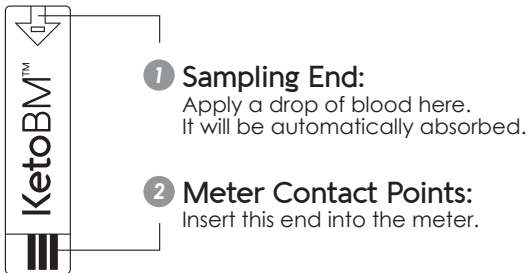


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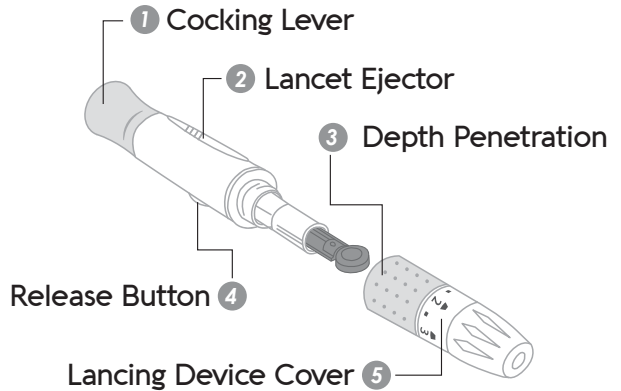
Display Screen



Ketone Test Strip



Lancing Device



Lancet



Changing Date and Time

(optional)

Step 1:

Open the battery cover and find the time adjust button located on the bottom left on the back of the meter.

Step 2:

Press and release the adjust button, the meter will turn on and the year will flash on the screen.

Step 3:

Press the enter button on the front side of the meter to adjust the year until the correct year is shown. Only the last two digits of the year are visible. For example, screen showing "17" is equal to year 2017.

Step 4:

Press and release the adjust button on the back of the meter to adjust the month.

Step 5:

Press the button on the front side of the meter until the correct month is shown.

Step 6:

Continue the same process of using the adjust and enter button to change the date, hour and minutes.

Step 7:

Press the adjust button and the meter will shut off automatically.

*Switch on bottom right is dormant and does not have a function

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Performing a Ketone Blood Test

Step 1: Wash Hands

Wash your hands with soap and water. Rinse and dry thoroughly.

Step 2: Load Lancing device

- (a) Twist off the end cap.
- (b) Insert the lancet.
- (c) Twist off the protective lancet cover.
- (d) Twist on the end cap.
- (e) Pull back the grey cocking mechanism.

Step 3: Insert Test Strip Into Monitor

Insert a KetoBM ketone test strip into the meter. Ensure that contact point side is being inserted into the meter with the arrow pointing down. Push the strip until it will go no further. The monitor will turn on automatically. The monitor will read 880 and a blinking blood drop will appear on the bottom of the screen.

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Step 4: Obtain Blood Drop

Place the lancing device against the side of your finger tip. Press the button to lance the finger. If necessary, gently squeeze your finger to help form a drop of blood.

Step 5: Apply Blood Drop To Test Strip








Apply the blood drop to the edge of the strip until the monitor beeps. This will start a countdown and your ketone result displays in 10 seconds. Discard the used lancet and test strip.

If your first readings come out high (above 4.0 mmol/L or HI) and you are not fasting, your test strip may be miscalibrated. Try another test strip and if the abnormal readings persist, contact support@ketobm.com for help.

Viewing Stored Readings From Memory

Your meter can store up to 180 ketone test results including the date and time. Turn on the meter using the enter button on the front side, then press the button to view readings from most recent to oldest. When the memory is full, the most recent result will be saved and oldest result will be deleted.

Troubleshooting

Display	Message	What it Means	What You Should Do
	E01	System error	Replace the batteries and test with a new strip. If the problem persists, please contact support@ketobm.com
	E02	Faulty or damaged test strip	Test with a new strip. If the error persists, contact support@ketobm.com
	E03	Incompatible test strip	Test again with an authentic KetoBM test strip.
	Battery symbol	Battery is low	Replace the battery soon
	Lo with battery symbol	No battery power	Replace the battery immediately, the meter will turn off automatically.
	Temperature symbol LO/HI	The room temperature is too low or too high for proper operation	Move to a location where the temperature is between 50-104°F (10°C-40°C) and wait for 20 minutes then test again with a new test strip.
	Hi with blood symbol	Blood ketone result may be too high (>8.0 mmol/L) or strip is miscalibrated	Test again with a new test strip. If the error message appears again, contact support@ketobm.com

Product Specifications

KetoBM Ketone Blood Monitoring System

Brand	KetoBM
System model	KBM-K01
Specimen	Capillary whole blood
Strip insert location	Top
Acceptable hematocrit range	30-60%
Measuring time	10 seconds
Operating temperature range	50°F - 104°F (10 - 40°C)
Relative humidity operating range	<85%
Strip model	KS - 01
Enzyme type	beta-Hydroxybutyrate Dehydrogenase(HBDH) Diaphorase(DAD)
Sample volume	0.5 uL
Measuring range	0.0 - 8.0 mmol/L
Storage condition - Temperature	39 - 86°F (4 - 30°C)
Meter model	KBM - K01
Memory capacity	180
Unit display	mmol/L
Time display	24 Hrs
Storage condition - Temperature	32 - 122°F (0 - 50°C)
Storage condition - Relative humidity	<95%
Dimension	87 x 63 x 23 (mm)
Weight	78 (g)
Power supply	AAA x 2

Product Warranty

KetoBM LLC warrants the KetoBM Meter to be free of defects in workmanship and materials under normal use for a period of two (2) years from the date of purchase to the consumer.

The liability of KetoBM LLC is limited to repair or replacement and in no event shall KetoBM LLC be liable for any collateral or consequential damages or loss. Products subjected to misuse, abuse, neglect, unauthorized repair or modification will be excluded from this warranty.

This guarantee specifically excludes expendables and consumables. The warranty applies only to the original purchaser of the system.

Test Principle

When the specimen (blood sample) is applied to 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

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

Pre-coded meter

There is no need to code the meter when it is pre-coded by default. For a pre-coded meter the new vial of strips has the same number as displayed on the screen of the meter. There's no need to use the code card and therefore the code card will not be provided.

A range of expected values

KetoBM Blood Ketone monitoring system detects levels of B-ketone, which comprise 78% of the ketone bodies present in blood. Expected blood ketone levels for a healthy individual would be less than 0.6 mmol/L. B-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 Ketone 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 fresh 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.

Limitations:

KetoBM 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
- The test result could be different from the laboratory result due to variance of normal distribution.
- 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 to clean the meter is acceptable cleaning solution include 70% ethanol.
- DO NOT remove test strip while the measurement is 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.
- Using 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



Do not re-use



Consult operating instructions



Keep dry



Consult accompanying documents



In-Vitro diagnostic



Operating temperature limitation



Store temperature limitation



Manufacturer



Manufacturing Date



Keep away from sunlight



Medical Device



Batch number



EU Representative

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



Paper Recycling



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

 **Lancet**  0197 and Lancing Device 

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No. 558 Zhangzikou, Yangsong Town,
Hoairou District, 101400 Beijing, China

EC REP

Lotus NL B.V.
Koningin Julianaplein 10, leVerd, 2595 AA, The Hague, Netherlands.

 **Lancet**  0123

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