

### β-Ketone & Blood Glucose Monitoring System

## **Owner's Manual**



## Dear Keto-Mojo System Owner:

Thank you for purchasing the Keto-Mojo  $\beta$ -Ketone & Blood Glucose Monitoring System. This manual provides important information to help you to use the system properly. Before using this product, please read the following contents thoroughly and carefully.

The system measures both blood glucose and  $\beta$ -ketone. Regular monitoring of your blood glucose and  $\beta$ -ketone levels can help you and your doctor gain better control of your diabetes. Due to its compact size and easy operation, you can use the Keto-Mojo  $\beta$ -Ketone & Blood Glucose Monitoring System to easily monitor your blood glucose and  $\beta$ -ketone levels by yourself anywhere, any time.

If you have other questions regarding this product, please contact

KETO-CHECK Customer Support at 800.513.1965 (10 am - 4 pm PST).

#### Intended Use

This Keto-Mojo  $\beta$ -Ketone & Blood Glucose system is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger, and for the quantitative measurement of  $\beta$ -Ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the finger. The system is intended for *in vitro* diagnostic use and for single-patient use as an aid to monitoring the effectiveness of a diabetes control program. The system should not be used for the diagnosis of, or screening for, diabetes, nor for use on neonates.

#### **Test Principle**

Your system measures the amount of glucose/ $\beta$ -ketone in whole blood. The glucose/ $\beta$ -ketone testing is based on the measurement of electrical current generated by the reaction of glucose/ $\beta$ -ketone with the reagent of the strip. The meter measures the current, calculates the glucose/ $\beta$ -ketone level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose/ $\beta$ -ketone in the blood sample.

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## IMPORTANT SAFETY INSTRUCTIONS READ BEFORE USE

- 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 biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For more information, please visit

 "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)

http://wayback.archiveit.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/ Safety/AlertsandNotices/ucm224025.htm

 "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)

http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

- Use this device ONLY for the intended use described in this manual.
- Do NOT use accessories which are not specified by the manufacturer.
- Do NOT use the device if it is not working properly or if it is damaged.

- 4. Do **NOT** under any circumstances use the device on the neonates.
- 5. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only.
- 6. Before using this device, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
- 7. Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
- 8. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as this may interfere with the accurate operation.
- 9. Proper maintenance and periodically control solution test are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact your local customer service or place of purchase for help.
- Use only Keto-Mojo Glucose Test Strips with Keto-Mojo β-Ketone & Blood Glucose Monitoring System to obtain accurate results, and be covered by the manufacturer's warranty.

#### **KEEP THESE INSTRUCTIONS IN A SAFE PLACE**

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## **BEFORE YOU BEGIN**

## Important Information

- If your blood glucose results or β-ketone are lower or higher than usual, and you do not have any symptoms of illness, first repeat the test. If you have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of your healthcare professional.
- Use only fresh whole blood samples to test your blood glucose or β-ketone. Using other substances will lead to inaccurate results.
- If you are experiencing symptoms that are inconsistent with your blood glucose or β-ketone test results and you have followed all the instructions given in this owner's manual, contact your healthcare professional.
- The device should not be used on severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a hyperglycemic- hyperosmolar state, with or without ketosis. Please consult the healthcare professional before use.

## Limitation

- The device should not be used on individuals in hyperglycemichyperosmolar state, with or without ketosis; not for neonatal use; not for use on critically ill patients.
- For over-the-counter use.
- The device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficincey Virus(HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other blood borne pathogens.

### Meter Overview



- ① Test Strip Slot / Strip Port Communication Insert test strip here to turn the meter on for testing. Connect strip port cable for data transmission.
- <sup>2</sup> Bluetooth Indicator Light
- <sup>③</sup> Display Screen
- <sup>④</sup> Main Button (M)
- 6 Test Strip Ejector Eject the used strip by pushing up this button.
- Bluetooth Switch Activate the Bluetooth function.
- SET Button (S) Enter and confirm the meter settings.
- 8 Battery Compartment

### **Display Screen**

1 Glucose Symbol (12) 2 **Ketone Symbol** Test Result (13) (3) (4)Error Message/ (14) **Ketone Waning**  $(\overline{5})$ Low Battery Symbol (15)  $(\widehat{6})$ **Day Average Memory Mode** (7)(8) Date / Time (9)Measurement Unit (10) Alarm Reminder (11) Auto QC Mode/ QC Mode QC- control solution test

Measuring Mode

AC – before meal PC – after meal Gen – any time of day **Test Strip Symbol** 

Blood Drop Symbol

#### Code



## Test Strip



- 1 Absorbent Hole
- 2 Confirmation Window
- 3 Test Strip Handle
- 4 Contact Bars



#### ATTENTION:

The front side of the test strip should face up and the contact bar should be fully inserted into the test slot in order to correctly turn on the meter and take measurements.

#### NOTE

- The Keto-Mojo monitor should only be used with Keto-Mojo Glucose or β-Ketone Test Strips. Using other test strips with this meter can produce inaccurate results.
- Do not use any other test strips including any other Keto-Mojo test strips or the result may be incorrect.

## Contents of System

- 1. Keto-Mojo β-ketone & blood glucose monitoring system
- 2. Keto-Mojo β-ketone test strips
- 3. Keto-Mojo glucose test strips
- 4. Lancing device
- 5. Lancets
- 6. Protective wallet
- 7. Batteries
- 8. Manual/instructions

Test strips (e), control solution (f), lancing device (g) or sterile lancets (h) are optional and may not be included in the kit (please check the contents in your product box). They can be purchased separately. Please make sure you have all items needed for a blood glucose or ketone test beforehand.

## SETTING THE METER

Before using your meter for the first time.

#### Entering the Setting Mode (a)

Start with the meter off (no test strip inserted). Press S.

#### 1. Setting the date

The sequence of the date setting is: YEAR  $\rightarrow$  MONTH  $\rightarrow$  DAY. With the YEAR / MONTH / DAY flashing in sequence, press **M** to select the correct number. Press **S**.

#### 2. Setting the time format

Press M to select the desired time format ---12h or 24h. Press S.

#### 3. Setting the time

With the HOUR / MINUTE flashing in sequence, press M until the correct hour/minute appears. Press **S**.

#### 4. Setting the unit of measurement

Press M to switch between mg/dL and mmol/L. Press S.

#### 5. Setting the buzzer

With the buzzer displays, press  ${\bf M}$  to switch between "On" and "OFF". Press  ${\bf S}.$ 

#### 6. Deleting the memory

With "dEL" and a flashing "  $\boxed{M}$  " on the display, press **M** and select "no" to keep the results in memory then press S to skip. To delete all the results, press **M** and select "yes" to delete all the memory records.

#### 7. Setting the reminder alarm

Your meter has four reminder alarms. The meter will display "OFF" and "AL1". If you don't want to set an alarm, press  $\bf{S}$  to skip this step; or press  $\bf{M}$  to select "On", then press  $\bf{S}$ .

With the hour/minute flashing in sequence, press  ${\bf M}$  to select the correct hour/minute. Press  ${\bf S}$  and go to the next alarm setting.

#### NOTICE:

When the alarm beeps, press M to switch it off. Otherwise, it will beep for 2 minutes then switch off.

#### 8. Setting the auto send (For Keto-Mojo)

Press **M** to select the auto-send ("AS") "On" or "OFF". Press **S**.

#### NOTICE:

When the alarm beeps, press M to switch it off. Otherwise, it will beep for 2 minutes then switch off.

#### 9. Setting the backlight

The default setting for meter backlight ("BL") is set to ON. Press M to switch between "On" and "OFF". Press S.

#### Congratulations! You have completed all settings!

#### NOTE:

- These parameters can **ONLY** be changed in the setting mode.
- If the meter is idle for 3 minutes during the setting mode, it will switch off automatically.

## THE MEASURING MODES

## For Blood Glucose Testing

The meter provides you with three modes for measuring, General, AC, and PC. You can switch between each mode by:

- Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display a flashing "♦" and "Gen".
- 2. Press **M** to switch between Gen, AC and PC mode.

## For $\beta$ -Ketone Testing

The meter provides you with one mode for measuring, General. You can start with the meter switched off. Insert a test strip to turn on the meter. The screen will display a flashing " 🌢 " and "Gen".

## **BEFORE TESTING**

## Calibration (for β-Ketone test)

You must calibrate the meter every time you begin to use a new vial of  $\beta$ -Ketone test strips by setting the meter with the correct code. Test results may be inaccurate if the code number displayed on the monitor does not match the number printed on the strip vial.

## How to Code Your Meter (for $\beta$ -Ketone test)(b)

1. Insert the code strip when the monitor is off. Wait until the code number appears on the display.

#### NOTICE:

Make sure the code number on display, code strip, and test strip vial are the same. The code strip should be within the expiry date; otherwise, an error message may appear. 2. Remove the code strip, the display will show "OK". This tells you that the meter has finished coding and is ready for  $\beta$ -ketone testing.

### Checking the Code Number (c)

You need to make sure that the code number displayed on the meter matches the number on your test strip vial before you proceed. If it matches, you can proceed with your test. If the codes do not match, please stop testing and repeat the calibration procedure. If the problem persists, contact Customer Service for help.

#### NOTICE:

The codes used in this manual are examples only; your meter may display a different code.

#### WARNING:

- It is important to make sure that the LCD displayed code is the same as the code on your test strip vial before testing. Failure to do so will get inaccurate results.
- The code number for β-Ketone strip is three-digits; please ensure you are using the correct strips for the test.
- If the LCD displayed code is not the same as the code on your test strip vial and the code number cannot be updated, please contact Customer Service for assistance.

## CONTROL SOLUTION TESTING

Our Control Solution contains a known amount of glucose/ $\beta$ -ketone that reacts with test strips and is used to ensure your meter and test strips are working together correctly.

#### Do a control solution test when:

- You first receive the meter
- At least once a week to routinely check the meter and test strips
- You begin using a new vial of test strips
- You suspect the meter or test strips are not working properly
- Your blood glucose or ketone test results are not consistent with how you feel, or if you think the results are not accurate
- Practicing the testing process, or
- You have dropped or think you may have damaged the meter

### Performing a Control Solution Test

To perform a control solution test, you will need: (d), (e) and (f).

#### 1. Insert the test strip to turn on the meter

Wait for the meter to display "  $\bigcirc$  " and "  $\blacklozenge$ ".

#### 2. Apply control solution (i)

Shake the control solution vial thoroughly before use. Squeeze out the first drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap. Hold the meter to move the absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will begin counting down.

#### NOTE:

- To avoid contaminating the control solution, do not directly apply control solution onto a strip.
- For blood glucose or β-ketone test, your device will tag this measurement as QC test automatically.

#### 3. Read and compare the result

After counting down to 0, the control solution test result will appear on the display. Compare this result with the range printed on the test strip vial and it should fall within this range. If not, please read the instructions again and repeat the control solution test.

With "QC" displayed, the meter will store your test result in memory under "QC".

#### **Out-of-range results**

If you continue to have test results fall outside the range printed on the test strip vial, the meter and strips may not be working properly. Do NOT test your blood and call customer service for help.

#### NOTE:

- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood test level.
- See the MAINTENANCE section for important information about your control solutions.

## TESTING WITH BLOOD SAMPLE

#### WARNING:

To reduce the chance of infection:

- Never share a lancet or the lancing device.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.
- Wash and dry your hands thoroughly after handling the meter, lancing device and test strips to prevent infection. For more information, please refer to the "Cleaning and Disinfection" section.
- If another person is assisting with the measurement and he or she is responsible for operating the meter, that person should clean and disinfect the meter and lancing device prior to the measurement.

Sharing the lancing device and lancets may increase the risk of contracting infectious diseases. Lancing device must not be used for more than one person.

### Preparing the Lancing Device for Blood Testing

Please follow the instructions in the lancing device insert for collecting a blood sample.

### Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction has a significant influence on the accuracy of the glucose or  $\beta$ -ketone value obtained. Blood from a site that has not been rubbed exhibits a measurably different glucose or  $\beta$ -ketone concentration than blood from the finger. If the puncture site was rubbed prior to blood extraction, the difference is significantly reduced.

## Please follow the suggestions below before obtaining a drop of blood:

- Select the puncture site at fingertips.
- Rub the puncture site for about 20 seconds before penetration.
- Clean the puncture site using cotton moistened with 70% alcohol and **let it air dry**.
- Fingertip testing

Press the lancing device's tip firmly against the lower side of your fingertip. Press the release button to prick your finger, then a click indicates that the puncture is complete.

#### NOTE:

Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.

Performing a Blood Glucose or  $\beta$ -Ketone Test To perform a blood glucose or  $\beta$ -ketone test, you will need: (d), (e), (g) and (h).

#### Insert the test strip to turn on the meter Wait for the meter to display the " " and " ", and "GLU" or "KETONE"

2. Select the appropriate measuring mode by pressing M.

#### 3. Obtaining a blood sample (j)

Use the pre-set lancing device to puncture the desired site. Wipe off the first appeared drop of blood with a clean cotton swab. The size of the drop should be at least as big as • (actual size), which is **1.0** microliter ( $\mu$ L) of volume. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample.

#### 4. Apply the sample (k)

Gently apply the drop of blood to the absorbent hole of the test strip at a tilted angle. Confirmation window should be completely filled if enough blood samples have been applied. Do **NOT** remove your finger until you hear a beep sound. Please refer to the System Troubleshooting section when you see the error message.

#### NOTE:

- Do not press the punctured site against the test strip or try to smear the blood.
- If you do not apply a blood sample to the test strip within 3 minutes, the meter will automatically turn off. You must remove and reinsert the test strip to start a new test.
- The confirmation window should be filled with blood before the meter begins to count down. **NEVER** try to add more blood to the test strip after the drop of blood has moved away. Discard the used test strip and retest with a new one.
- If you have trouble filling the confirmation window, please contact your health care professional or the local customer support for assistance.

#### 5. Read Your Result

The result of the blood glucose or  $\beta$ -ketone test will appear after the meter counts down to 0. The result will be stored in your memory automatically. If your test result is lower than expected using the keto-Mojo meter, contact your healthcare professional immediately for the further testing.

#### 6. Remove the used test strip and lancet (I)

Eject your test strip by pushing the eject button on the side. Use a sharp bin to dispose of used test strips. The meter will switch itself off automatically.

## Always follow the instructions in the lancing device insert when removing the lancet.

#### WARNING:

- The used lancet and test strip may be biohazardous. Please discard them carefully according to your local regulations.
- Wash your hands thoroughly with soap and water after handling the meter, lancing device and test strips to avoid contamination. For more information, please refer to the "Cleaning and Disinfection" section.

## METER MEMORY

This meter stores the **1000** most recent blood glucose/ $\beta$ -ketone test results, dates and times in its memory. To enter the meter memory, **start with the meter switched off**.

## **Reviewing Test Results**

#### 1. Press and release M.

" $\mathbb{M}$ " will appear on the display. Press **M** again, and the first reading you see is the last blood glucose or  $\beta$ -ketone result along with date, time and the measuring mode.

 Press M to recall the test results stored in the meter each time you press. After the last glucose or β-ketone test result, press M again and the meter will switch off.

## Reviewing Blood Glucose Day Average Results

- Press and release M. When " m " appears on the display, keep pressing M for 3 seconds until the flashing "DAY AVG" appears. Release M and then your 7-day average result measured in general mode will appear on the display.
- 2. **Press M to review** 14-, 21-, 28-, 60- and 90- day average results stored in each measuring mode in the order of Gen, AC, and then PC.
- 3. Exit the meter memory.

Keep pressing the  ${\bf M}$  and the meter will switch itself off after displaying the last test result.

#### NOTE:

- Any time you wish to exit the memory, keep pressing **M** for 3 seconds or leave it without any action for 3 minutes. The meter will switch off automatically.
- Control solution results are NOT included in the day average.

## **BLUETOOTH PAIRING**

### Data Transmission via Bluetooth

You can transmit your data from the meter to your device via Bluetooth. The **Keto-Mojo app** is designed to assist you easily monitoring your blood glucose, and  $\beta$ -ketone levels.

#### How to Install and Update the Keto-Mojo app

You must connect to the internet to download the app. The APP Store or Google Play can be accessed by tapping the APP Store or Play Store icon on your iOS or Android devices.

It is simple and intuitive to use, for better understanding of your current condition and to achieve better diabetes or  $\beta$ -ketone control.

#### System Requirement

For the requirement of OS version, please find on App Store or Google Play when you download the app. Please contact your local customer support or place of purchase for assistance. Please note that you must complete the pairing between meter and Bluetooth receiver before transmitting data.

#### Pairing with Your Mobile Device

- 1. Turn on the Bluetooth function on your mobile device.
- 2. With the meter off, push the Bluetooth switch for 3 seconds to turn Bluetooth on.
- 3. Follow the instruction of the Keto-Mojo app to pair the device. (Ex: Search to find the meter and then add it into app.)
- 4. After successfully pairing the app with the device, the Bluetooth function of meter shall be on before transmitting the data to the Keto-Mojo app.

#### Bluetooth Indicator on the Blood Glucose Keto-Mojo Meter:

BLUETOOTH INDICATOR	STATUS
Flashing Blue	The Bluetooth function is on and waiting for connection.
Solid Blue	The Bluetooth connection is established.

#### WARNING:

- While the meter is in transmission mode, it will be unable to perform a test.
- Make sure your device supports Bluetooth Smart Technology. Also make sure the Bluetooth setting on your device is turned on and the meter is within the receiving range before transmitting the data. Please find OS version requirement on App Store or Google Play when you download the app.
- The Bluetooth functionality is implemented in different ways by the various mobile device manufacturers; the compatibility issue between your mobile device and the meter may occur.

## MAINTENANCE

### Battery

Your meter comes with two 1.5V AAA size alkaline batteries.

#### Low Battery Signal

The meter will display one of the messages below to alert you when the meter power is getting low.

- 1. **The "I**" **symbol appears**. The meter is functional and the result remains accurate, but it is time to change the batteries.
- 2. The "**I**" symbol appears with E-b, Error and "<u>A</u>": The power is not enough to do a test. Please change the batteries immediately.

#### Replacing the Battery (m)

#### To replace the batteries, make sure the meter is turned off

- 1. Press the edge of the battery cover and lift it up to remove.
- 2. Remove the old batteries and replace with two 1.5V AAA size alkaline batteries.
- 3. Close the battery cover. If the batteries are inserted correctly, you will hear a "beep" afterwards.

#### NOTE:

- Replacing the batteries does not affect the test results stored in the memory.
- As with all small batteries, these batteries should be kept away from children. If swallowed, promptly seek medical assistance.
- Batteries might leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more).
- Properly dispose of the batteries according to your local environmental regulations.

### Caring for Your Meter

To avoid the meter and test strips attracting dirt, dust or other contaminants, please wash hands thoroughly with soap and water before and after use.

#### Why the cleaning and disinfection should be performed

Cleaning and disinfection are different. Cleaning is the process of removing dirt (e.g. food debris, grease, dust), while disinfection is the process of killing germs (e.g. bacteria and viruses). Routine cleaning/disinfect should be undertaken once a week.

#### When to clean and disinfect the meter

Clean the meter when you see any dirt on it. You should disinfect the meter at least once a week to prevent infection.

#### How to clean and disinfect the meter

The meter must be cleaned prior to the disinfection. Use one disinfecting wipe to clean exposed surfaces of the meter thoroughly and remove any visible dirt or blood or any other body fluid with the wipe. Use a second wipe to disinfect the meter. **Do NOT use organic** 

#### solvents to clean the meter.

We recommend for meter cleaning and disinfection you should use the disinfecting wipes/towelettes from below. The following product with isopropyl alcohol as the active ingredient has been shown to be safe for use with the blood glucose plus  $\beta$ -ketone monitoring system:

 Micro-Kill<sup>+</sup>™ (Micro-Kill Plus<sup>™</sup>) by Medline (EPA Reg. No. 59894-10-37549)

To obtain disinfecting wipes and other information, please contact Medline at 1-800-MEDLINE (1-800-633-5463) or visit <u>https://athome.medline.com/</u>. You can also purchase it at Amazon (www.amazon.com) or Walmart (www.walmart.com).

### **Disinfecting Procedures**

- Wipe all meter's exterior surface display and buttons by three passes vertically and three passes horizontally with a folded disinfecting towelette. Hold the meter with the test strip slot pointing down and wipe the area around the test slot but be careful not to allow excess liquid to get inside. Keep meter wet with disinfection solution contained in the wipe for a minimum of 2 minutes for Micro-Kill+™ wipes. (n)
- 2. Dispose of the used wipe. Allow the meter surface to dry completely.
- 3. Discard the used wipes and never reuse them. Users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

Improper system cleaning and disinfection may result in meter malfunction. If you have a question, please contact local customer service at 1-888-307-8188 for assistance.

This device has been validated to withstand up to 10950 cleaning and disinfection cycles using the recommended disinfecting wipe/towelette. The tested number of cycles is estimated by 10 cleaning and disinfection cycles per day over 3 years. The meter should be replaced after the validated number of cleaning and disinfection cycles or the warranty period, whichever comes first.

Stop using the meter if you see any signs of deterioration. For example:

- Meter cannot be turned on
- LCD display cracks or becomes cloudy
- Buttons no longer function
- Meter outer casing cracks
- Data cannot be transmitted to pc
- Color or paint/printing on housing is abnormal
- Scratches or abrasions on meter are higher than acceptable

Please contact the customer service for a replacement meter if any of the signs of deterioration are noticed.

#### NOTE:

- Do NOT clean and disinfect the meter while performing tests.
- If another person is assisting with the measurement and he or she is responsible for operating the meter, that person should clean and disinfect the meter and lancing device prior to the measurement.
- Do NOT allow cleaning and disinfecting solution to get in the test slot, battery compartment, or strip-ejection button.
- If you do get moisture in the test strip slot, wipe it away with a corner of tissue.
- Always dry the meter thoroughly before using it.
- Do not spray the meter directly with cleaning solutions especially those containing water (i.e. soapy water), as this could cause the solution to enter the case inside and damage the electronic components or circuitry.

## Caring for Your Test Strips

- Storage conditions: 35.6°F to 86.0°F (2°C to 30°C), between 10% and 85% relative humidity (non-condensing). Do **NOT** freeze.
- Store your test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately close the vial cap tightly.
- Touch the test strip with clean and dry hands. Use each test strip immediately after removing it from the vial.
- Use each test strip immediately after removing it from the vial.
- $\bullet$  Write the opening date on the vial label when you first opened it. Discard remaining blood glucose or  $\beta\text{-ketone}$  test strips after 6 months
- Do not use test strips after the expiration date. This may cause inaccurate results.
- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

For further information, please refer to the test strip package insert.

### Important Control Solution Information

- Use only our control solutions with your meter.
- Do not use the control solution beyond the expiration date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature 68°F to 77°F (20°C to 25°C). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.
- Store the control solution tightly closed at temperatures between 35.6°F to 86.0°F (2°C to 30°C). Do **NOT** freeze.

## MEASUREMENT RESULTS READINGS

### For Blood Glucose Test

MESSAGE	WHAT IT MEANS
Ľo	< 10 mg/dL (0.56 mmol/L)
	10 mg/dL - 239 mg/dL (0.56 mmol/L - 13.2 mmol/L)
	≥ 240 mg/dL (13.3 mmol/L) The User's blood glucose level has exceeded 240 mg/dL (13.3 mmol/L), possible of ketoacidosis. Please consult with the healthcare professionals for further inspection. Source: Abbas E. Kitabchi et al., Diabetes Care. 2009 Jul; 32(7): 133532(7): 1335–1343.
<sup>ан</sup> Н ,	>700 mg/dL (38.89 mmol/L)

### For $\beta$ -ketone Test

MESSAGE	WHAT IT MEANS
LO	< 0.1 mmol/L
	0.1 to 8.0 mmol/L
	> 8.0 mmol/L

### **Detailed Information**

Blood glucose plus  $\beta$ -ketone monitoring plays an important role in diabetes control. A long-term study showed that maintaining **blood glucose levels close to normal** can reduce the risk of diabetes complications by up to 60%\*1. The results provided by this system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Condition	Normal plasma glucose range (mg/dL)
Fasting and before meal	Less than 100 mg/dL (5.6 mmol/L)
2 hours after meals	Less than 140 mg/dL (7.8 mmol/L)

\*<sup>1</sup>: American Diabetes Association, Standards of Medical Care in Diabetes, Volume 41, Supplement 1, January 2018

The  $\beta$ -Ketone test measures Beta-Hydroxybutyrate ( $\beta$ -OHB), the most important of the three  $\beta$ -Ketone bodies in the blood. Normally, levels of  $\beta$ -OHB are expected to be less than 0.6 mmol/L.

 $\beta$ -OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill. If your  $\beta$ -Ketone result is "Lo", repeat the  $\beta$ -Ketone test with new test strips. If the same message appears again or the result does not reflect how you feel, contact your healthcare professional. Follow your healthcare professional's advice before you make any changes to your diabetes medication program. If your  $\beta$ -Ketone result is between 0.6 and 1.5 mmol/L, this may indicate development of a problem that could require medical assistance. Follow your healthcare professional's instructions. If your  $\beta$ -Ketone result is higher than 1.5 mmol/L, contact your healthcare professional promptly for advice and assistance. You may be at risk of developing diabetic ketoacidosis (DKA).

## Please consult your doctor to determine a target range that works best for you.

### Comparing Meter and Laboratory Results

The meter provides you with whole blood equivalent results. The result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results may be affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between meter and laboratory results, follow the guidelines below.

#### Before going to the lab:

- Perform a control solution test to make sure that the meter is working properly.
- Fast for at least eight hours before doing comparison tests, if possible.
- Take your meter with you to the lab.

#### While staying at the lab:

Make sure that the samples for both tests are taken and tested within 15 minutes of each other.

- Wash your hands before obtaining a blood sample.
- Never use your meter with blood that has been collected in a gray-top test tube.
- Use fresh capillary or venous blood only.

You may still have a variation from the result because blood glucose or  $\beta$ -ketone levels can change significantly over short periods of time, especially if you have recently eaten, exercised, taken medication or experienced stress<sup>\*2</sup>. In addition, if you have eaten recently, the blood glucose level from a finger prick can be up to 70 mg/dL (3.9 mmol/L) higher than blood drawn from a vein (venous sample) used for a lab test<sup>\*3</sup>. Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (dehydration) may also cause a meter result to be different from a laboratory result.

\*2: Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast (1988), April, 49-51.

\*3: Sacks, D.B.: "Carbohydrates. " Burtis, C.A., and Ashwood, E.R.(ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959.

## SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, please contact your local customer service.

### **Error Messages**

MESSAGE	WHAT IT MEANS	WHAT TO DO
E-b	Appears when the battery is too low.	Replace the battery immediately.
E-2	Appears when the test strip/code chip is expired.	Check the expiry date of the strip; repeat the test with a new lot of test strip if necessary. Also make sure that the date you input to the meter is correct.
E-U	Appears when a used test strip is inserted.	Repeat with a new test strip.
E-t	Appears when ambient temperature is above or below system operation range.	System operation range is 10°C to 40°C (50°F to 104°F). Repeat the test after the meter and test strip are in the above temperature range.
E-F	Appears when test strip is removed while counting down, or insufficient blood volume.	Review the instructions and repeat test with a new strip. If the problem persists, please contact the local customer service for help.
E-0 E-A E-E E-C	Problem with the meter.	Repeat the test with a new test strip. If the meter still does not work, please contact Keto-Mojo Customer Support for assistance.

## Troubleshooting

1. If the meter does not display a message after inserting a test strip:

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Replace the batteries.
Test strip inserted upside down or	Insert the test strip with contact bars
incompletely.	end first and facing up.
	Please contact Keto-Mojo Customer
Defective meter or test strips.	Support for assistance.

2. If the test does not start after applying the sample:

POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test using a new test strip
	with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic	Repeat the test with a new test strip.
switch-off (3 minutes after last	Apply sample only when flashing "
user action).	appears on the display.
Defective motor	Please contact Keto-Mojo Customer
	Support for assistance.

3. If the control solution testing result is out of range:

POSSIBLE CAUSE	WHAT TO DO
	Read instructions thoroughly and
End in pendining the test.	repeat the test again.
Control solution vial was poorly	Shake the control solution vigorously
shaken.	and repeat the test again.
Expired or contaminated control	Check the expiry date of the control
solution.	solution.
Control solution that is too warm or too cold.	Control solution, meter, and test strips
	should be at room temperature 20°C to
	25°C (68°F to 77°F) before testing.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact Keto-Mojo Customer
	Support for assistance.
Improper working of meter and	Please contact Keto-Mojo Customer
test strip.	Support for assistance.

## **SPECIFICATIONS**

Model No.: Keto-Mojo Dimension & Weight: 96 (L) x 61 (W) x 26 (H) mm, 67.2 g Power Source: Two 1.5V AAA alkaline batteries Display: LCD Memory: 1000 measurement results with respective date and time External Output: Bluetooth

Auto electrode insertion detection Auto reaction time count-down Auto switch-off after 3 minutes without action Temperature Warning

# **Operating Condition:** $50^{\circ}F$ to $104^{\circ}F$ ( $10^{\circ}C$ to $40^{\circ}C$ ), and 10% to 85% R.H. (non-condensing)

#### Meter Storage/Transportation Conditions:

-4°F to 140°F (-20°C to 60°C), below 93% R.H. (non-condensing)

#### Strip Storage/Transportation Conditions:

glucose test strip: 35.6°F to 86°F (2 °C to 30°C ) and 10% to 85% R.H. β-ketone test strips: 35.6°F to 86°F (2 °C to 30°C) and 10% to 85% R.H.

#### Measurement Units:

Blood Glucose Test: Either mg/dL or mmol/L  $\beta$ -ketone Test: Fixed mmol/L

#### Measurement Range:

Blood Glucose Test: 10 to 700 mg/dL (0.56 to 38.89 mmol/L)  $\beta$ -ketone Test: 0.1 to 8.0 mmol/L

#### Expected Service Life: 5 years

The Keto-Mojo  $\beta$ -ketone & blood glucose monitoring system is intended for use in the home environment. The customer or user of the system should ensure that it is used in such an environment.

Manufactured for: Keto-Check Inc, 952 School St. Suite 212 Napa, CA 94559-2824 Tel: 800.513.1965 10am-4pm PST Please contact your healthcare provider outside hours of operation. www.Keto-Mojo.com

For Self-testing. Read instructions before use.