English

GK+ Blood Glucose and β-Ketone Dual Monitoring System

Dear **Keto-Mojo®** System User,

Thank you for choosing the **Keto-Mojo® GK+** Blood Glucose and β-Ketone Dual Monitoring System! The **Keto-Mojo® GK+** Blood Glucose and β-Ketone Dual Monitoring System is designed for easy and accurate testing of blood glucose and β-ketone levels.

Read this User's Manual carefully before you use your system. This manual will help you use the system properly for reliable test results. Please keep your User's Manual in a safe place, as you may want to refer to it in the future. You will also want to keep the meter box (and any strip boxes you purchase) as your control solution test ranges are printed or stickered on the box. You will also find manuals and other resources, such as instructional videos, at keto-mojo.com.

Thank you again for choosing the **Keto-Mojo®** GK+ Blood Glucose and β-Ketone Dual Monitoring System.

Test Principle and Intended Use

The **Keto-Mojo® GK+** Blood Glucose and β-Ketone Dual Monitoring System is comprised of the **Keto-Mojo® GK+** Blood Glucose and β-Ketone Meter, **Keto-Mojo®** Blood Glucose Test Strips and **Keto-Mojo®** Blood β-Ketone Test Strips. The glucose measurement is achieved by using the amperometric detection method. The test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is pulled into the tip of the test strip through capillary action. Glucose in the sample reacts with glucose enzyme and the mediator. Electrons are generated, producing a current that has positive correlation to the glucose concentration in the sample. After the reaction time, the glucose concentration in the sample is displayed.

The test principle of the β-ketone is based on the amperometric detection of β-hydroxybutyrate (also known as 3-hydroxybutyrate) in whole blood. β-hydroxybutyrate is converted by the enzyme β-hydroxybutyrate dehydrogenase

to acetoacetate. The magnitude of electrical current resulting from this enzymatic reaction is proportional to the amount of β-hydroxybutyrate present in the sample.

The **Keto-Mojo® GK+** Blood Glucose and β-Ketone Dual Monitoring System is intended to quantitatively measure the glucose concentration and/or β-ketone (beta-hydroxybutyrate) concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of, or screening for, diabetes. This system is intended for self-testing outside the body (*in vitro* diagnostic use) and should only be used by a single person and should not be shared.

The meter is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part pf glycemic control procedures. Use of this system on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

TABLE OF CONTENTS

CHAPTER 1: UNDERSTANDING YOUR TESTING TOOLS

Your Meter System Overview

The **Keto-Mojo® GK+** Blood Glucose and β-Ketone Meter and Test Strips

Inserted individually, the **Keto-Mojo® GK+** Blood Glucose & β-Ketone Meter reads both glucose and ketone test strips.

BLOOD SAMPLE TIP

Where the blood is drawn in.

ELECTRODE END

This end is inserted into the test strip port on the meter with the electrode facing up.

STRIP PORT

Insert a test strip in the strip port at the top of the meter.

The strip port light turns on automatically when the meter is on.

DISPLAY

Shows test results, messages and related information.

MAIN/POWER BUTTON

Press to turn meter on/off. Use to switch between functions and to set settings.

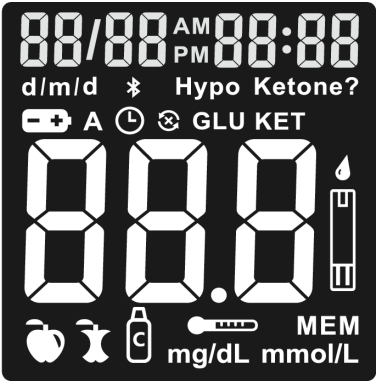
SIDE BUTTONS

Toggle between various functions and settings.

Your Meter Display

The picture below shows all of the symbols that may appear on your meter display. Please make sure the display is working properly before testing. When the meter is off, press and hold the **power button** to see the complete display. All display segments will appear. If you need more time to check the display, repeat the operation.

All of the segments should be clear and look exactly like the picture below. If not, contact **Keto-Mojo** at 800-513-1965 (5 days a week, 10am-4pm PST) for further assistance. Please contact your healthcare professional if you need help outside of these hours.



Icon	What it Means
88/88	The top left area on the screen indicates the date.
88:88	The top right area on the screen indicates the year or time.
AM PM	The top middle area on the screen indicates morning or afternoon time.
d/m/d	Indicates the display form of date and month (d/m or m/d), or month and year.
	Indicates successful Bluetooth communication.
	Indicates failed Bluetooth communication.
	Indicates the alarms have been set.

GLU	Blood Glucose test mode.
KET	Blood β-Ketone test mode.
	Indicates low batteries or batteries need to be replaced.
A	Indicates average value.
MEM	Indicates test result history.
	Center area on the display that shows test results or error codes.
	Indicates that the system is ready to test.
	Control test result.
	Pre-meal marker.
	Post-meal marker.
mg/dL mmol/L	Blood glucose test results are displayed as mg/dL and blood β-ketone test results are displayed as mmol/L.
	Indicates the temperature is not suitable for testing.
Ketone?	Ketone warning.
Hypo	Indicates that a low test result may cause hypoglycemia.

Notes:

*Your **Keto-Mojo® GK+** Blood Glucose and β-Ketone Meter is pre-set with a beep sound. The meter will beep when:*

- *You turn on the meter.*
- *You set the date and time.*
- *You set the test mode.*
- *The test strip is inserted and is ready to apply blood or control solution.*
- *Sufficient blood or control solution is pulled into the test strip.*
- *The test is complete.*
- *It is time to perform a test if you set the test alarms.*
- *If any error occurs during operation.*

Meter Use and Precautions

- The meter is preset to display blood glucose concentration in milligrams per deciliter (mg/dL) by default. The meter is preset to display blood β-ketone concentration in millimoles per liter (mmol/L) by default. The ketone unit of measure cannot be adjusted.
- Do not get water or other liquids inside the meter.
- Keep the strip port area clean.
- Keep your meter dry and avoid exposing it to extreme temperatures or humidity.
- Do not leave it in your car.
- Do not drop the meter or get it wet. If you do drop the meter or get it wet, check the meter by running a quality control test. Refer to **Testing with Control Solution** for instructions.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Refer to the **Caring for Your Monitoring System** section for details on cleaning the meter.
- Keep the meter and all associated parts out of reach of children.

Note: Follow proper precautions and all local regulations when disposing of the meter and used batteries.

Important Safety Information

- The meter is for single patient use. Do not share with anyone, including other family members! Do not use on multiple patients!
- Do not use the meter if it is dropped into water or water splashes on it.
- Wash and dry your hands well before and after testing.
- Test strips and lancets are for single use only.
- Do not drop blood directly on the flat surface of the test strip.
- Check the expiration dates on your test strips foil pouch and control solution bottle label.
- Use only **Keto-Mojo®** Blood Glucose/ **Keto-Mojo®** Blood β-Ketone Test Strips with your **Keto-Mojo® GK+** Blood Glucose and β-Ketone Meter.
- Use only **Keto-Mojo®** Blood Glucose/ **Keto-Mojo®** Blood β-Ketone Control Solution with your **Keto-Mojo® GK+** Blood Glucose and β-Ketone Meter and **Keto-Mojo®** Blood Glucose/ **Keto-Mojo®** Blood β-Ketone Test Strips.
- Please contact your physician or diabetes healthcare professional if you decide to make changes to your current medical therapy or diet activity based on test results.
- If the system is used in a manner not specified by the manufacturer, the protection provided by the system can be impaired.

Potential Biohazard

All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

1. 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!
2. All parts of the kit are considered biohazardous. They can potentially transmit infectious diseases from bloodborne pathogens, even after you have performed cleaning and disinfection. Please follow proper precautions when handling your meter.
3. For more information, please refer to the FDA Public Health Notification: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm. You may also refer to the CDC Clinical Reminder: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) at http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html.

Limitations

- For single patient use only.
- Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results for blood glucose testing, and very high (above 65%) and very low (below 20%) hematocrit levels can cause false results for blood β-ketone testing. Talk to your healthcare professional to understand your hematocrit level.
- Do not use this system if you are taking vitamin C (ascorbic acid in your blood > 3 mg/dL) since it could cause your glucose and ketone results to be incorrect.
- Patients undergoing oxygen therapy may produce false results.
- Severe dehydration (excessive water loss) may cause inaccurate results.
- Not for neonatal use.
- Not for use on patients with critical illness.
- Not for use in severely hypotensive individuals or on patients in shock or in a hyperosmolar state.
- Not for screening or diagnosis of diabetes.
- Do not use the system at altitudes above 13,123ft (4,000 meters) above sea level for testing.
- Do not use when humidity is higher than 90% and lower than 10%, as extremes in humidity may affect results.
- For *in vitro* diagnostic use only.
- The meter is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.

CHAPTER 2: SETTING UP YOUR SYSTEM

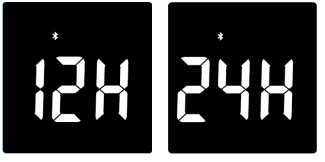
Before you use your meter for the first time or if you change your meter batteries, you should check and update your meter settings.

Set the Date and Time Manually

Note: *Before your first use of the meter for testing, it is important to adjust the meter settings to set the correct date and time, ensuring that results stored in the memory are captured correctly.*

1. Enter the setting mode and set the clock

When the meter is off, press and hold the **power button** for more than 2 seconds until the meter beeps to enter the set-up mode. Press the **side button** to adjust and set the clock for 12- or 24-hour mode, then press the **power button** to save your choice. Now you can proceed to set the date.



2. Set the date

The year will now flash on the display. Press the **side button** to adjust it until the year setting is completed, then press the **power button** until the meter beeps to set.

The display form of date and month will now flash, press the **side button** to set the date display form for m/d or d/m mode, then press the **power button** to save your choice. Start setting the month.

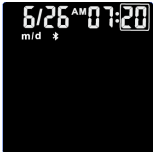
The month will now flash. Press the **side button** to adjust the month until the month setting is completed, then press the **power button** until the meter beeps to set.

The day will now flash. Press the **side button** to adjust the day until the date setting is completed, then press the **power button** until the meter beeps to set.

3. Set the Time

The hour will now flash. Press the **side button** to adjust the current hour until the hour setting is completed, then press the **power button** until the meter beeps to set.

The minute will now flash. Press the **side button** to adjust the minute until the minute setting is completed.



Set the Beep Feature

After setting the date and time, press the **power button** until the meter beeps and the word ‘beep’ flashes on the screen. Press the **side button** to set On or OFF, press the **power button** to save the beep setting.

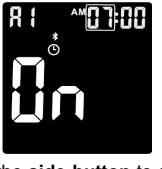
Set the Test Alarm

After the audio setting is completed, the meter will enter the test alarm setting mode; this function reminds users to take a measurement. Your meter is pre-set with the test alarm function to “OFF,” however, you can set up to 5 reminders per day. If you turn 5 test alarms on (A1, A2, A3, A4 and A5), your meter is pre-set with the following times for your convenience; you can adjust each time to suit your needs.

A1 7:00 A2 9:00 A3 14:00 A4 18:00 A5 22:00

Before you set the time, the ⏲ and the word “OFF” will be displayed, the symbol “A1” flashes. Press the **side button** to turn the alarm function on or off and press the **power button** to save.

If you select “On” the hour flashes “A1” and the ⏲ remains on the display. Press the **side button** to select the hour. Press the **power button** to set.



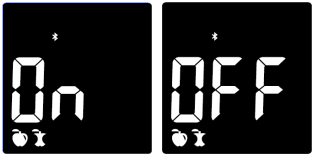
When the minutes flash, press the **side button** to select 00, 15, 30, or 45. These are the only choices. Press the **power button** to set.

The next alarm “A2” flashes on the display with an “OFF.”

You can now set a second alarm by pressing the **side button** to turn on the second alarm. Do the same procedures to set the rest of the alarms.
Note: *If the meter is on at the test reminder time, the test alarm will not be activated.*

Set the Meal Marker

After setting the test alarm functions, the symbol of will now flash, along with word “On” on the display. The Meal Marker allows you to tag your glucose test either “before meal” (whole apple icon) or “after meal” (eaten apple icon). Press the **side button** to turn the meal marker function On or Off, press the **power button** to set.



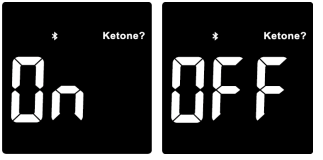
Set the Hypoglycemia (Hypo) Warning

After setting the meal marker, you can set the hypo alarm, which indicates a possible hypoglycemic condition (blood glucose level is too low).
Before you set the hypo alarm, the **Hypo** flashes along with “On” on the display. Press the **side button** to turn the Hypo alarm function on or off, press the **power button** to set. If you select the hypo alarm “On” the display shows 70 mg/dL with the symbol of “GLU.” Press the side buttons to change your glucose level up or down and press the **power button** to set.

Note: *Talk to your healthcare professional to help you decide the hypo level that suits your health condition.*

Set the Ketone Warning

After the hypo warning setting is completed, the **Ketone?** symbol will now flash, along with word “On” on the display. Press the **side button** to turn the Ketone Warning on or off, then press the **power button** to set.



After setting the Ketone Warning, the screen will now show all of the symbols you have set. Press the **power button** and the meter will turn off.

Once all the settings are completed, if you want to change the settings, please press and hold the **power button for 2 seconds** when the **Keto-Mojo® GK+** Blood Glucose and β-Ketone Meter is off, and then return to the setting mode.

Pairing Your Meter with a Smartphone

Pairing allows your **Keto-Mojo® GK+** Blood Glucose and β-Ketone Meter and Smartphone to communicate with each other.

Instructions for pairing your meter with the **Keto-Mojo** iOS and Android App can be found by either scanning the QR code below, or by typing the following weblink into a new browser tab:
https://keto-mojo.com/bluetooth-app-connection/

Follow the guidelines and instructions to successfully pair the meter with the **Keto-Mojo** App. Please note that data and reports in the App are not used for medical care reference by user or healthcare professionals.

SCAN ME

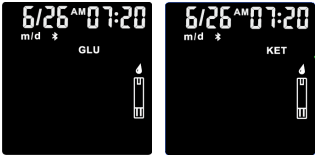
CHAPTER 3: PERFORMING A TEST

Set up your meter correctly and have all the materials ready before you begin testing. This includes your **Keto-Mojo® GK+** Blood Glucose and β-Ketone Meter, **Keto-Mojo®** Blood Glucose Test Strips, **Keto-Mojo®** Blood β-Ketone Test Strips and **Keto-Mojo®** Lancing Device and Lancets.

Preparing the Test Strip

1. Wash and dry your hands before testing.
2. Take a test strip from the test strip foil pouch.
3. Insert the test strip into the meter in the direction of the arrow.

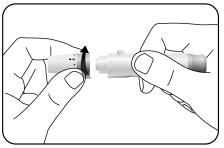
4. The meter is ready to test when a test strip symbol with a flashing blood drop appears.

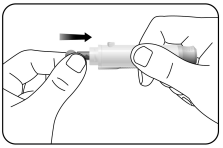


Note: *Check the expiration and discard dates on the test strip foil pouch. All expiration dates are printed in Year-Month-Day format: 2021-01-15 indicates January 15, 2021. Make sure the test strip does not appear damaged. Prior to testing, wipe and dry the test site of fingertip with a* ***Keto-Mojo®*** *alcohol prep pad or soapy water. Make sure there is no cream or lotion on the test site.*

Preparing the Lancing Device

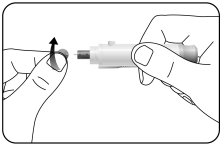
1. Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancing device and push it in until the lancet comes to a complete stop in the lancing device.



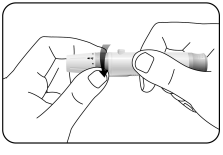


Note:
*The **Keto-Mojo®** lancing device uses **Keto-Mojo®** sterile lancets.*

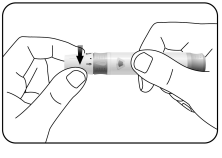
2. Hold the lancet firmly in the lancing device and twist the safety tab of the lancet until it loosens, then pull the safety tab off the lancet. Save the safety tab for disposing of the used lancet.

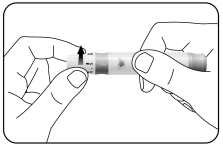


3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully sealed on the lancing device.



4. Adjust the puncture depth by rotating the lancing device cover. There are several different puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.





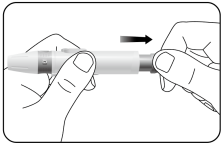
Adjustment:

1	for delicate skin
2 and 3	for normal skin
4 and 5	for calloused or thick skin

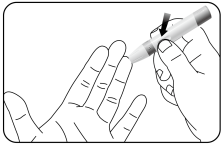
Note: *Greater pressure of the lancing device against the puncture site will also increase the puncture depth.*

Getting a Blood Drop for Testing

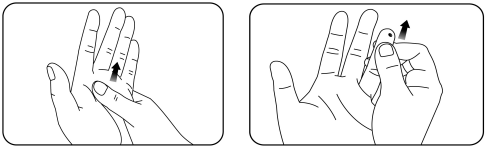
1. Pull the cocking device back to set the lancing device. You may hear a click to indicate the lancing device is now loaded and ready for obtaining a drop of blood.



2. Press the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your finger. You should hear a click when the lancing device activates.



3. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid touching or smearing the drop of blood. For the greatest reduction in pain, lance on the side of the fingertips. Test immediately after a blood drop has formed.



4. Immediately touch the tip of the test strip to the drop of blood. Do not press into the finger, as the strip needs air in order to draw in the blood. The blood will get pulled into the test strip through the tip. Make sure that the blood sample has fully filled the check window of the tip of the strip. Hold the tip of the test strip in the blood drop until the meter beeps.

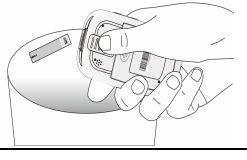
Note: *If the blood sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.*

5. For blood glucose testing, the meter counts down from 5 to 1, and for blood β-ketone testing, the meter counts down from 9 to 1. The result then appears on the display and the test result will automatically be stored in the meter memory. If you have the Meal Marker turned on in settings the ( ) flashes when your glucose reading displays. Use the side buttons to select the pre- or post- meal icon and press the power button to set. Please do not touch the test strip during the countdown as this may result in an error.

6. After the reading displays, discard the first test strip (see below). If the first test was glucose, insert a ketone test strip and bring the tip of the test strip to the blood droplet. You can take both tests from the same droplet.

Discarding the Used Test Strip

You can eject and discard the used test strip by using the strip ejector. The meter turns off automatically after a beep.



Potential Biohazard

Dispose of the used test strips as medical waste

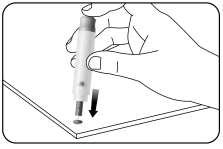
Note:

1. *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!*

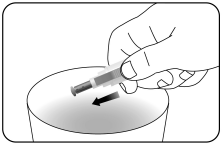
2. *All parts of the kit are considered biohazardous. They can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection. Please follow proper precautions when handling your meter and lancing device.*

Removing the Used Lancet

Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface and insert the lancet needle into the safety tab.



Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to discard the used lancet. Place the lancing device cover back on the lancing device.



Potential Biohazard

Always dispose of the used lancet properly to prevent injury or contamination to others.

Caution:

- *Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.*
- *Do not use the lancet if the needle is bent.*
- *Be cautious whenever the lancet needle is exposed.*
- *Never share lancets or the lancing device with other people to prevent possible infections.*
- *In order to reduce the risk of infection, always use a new and sterile lancet. Do not reuse lancets.*
- *Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt or debris.*

Expected Blood Glucose/β-Ketone Control Goal

1. Blood Glucose Reference Ranges

Expected blood glucose values for people without diabetes:[1]

Time of Day	Glucose Range
Fasting and before meals	<100 mg/dL
2 hours after meals	<140 mg/dL

Warning:

- *If your blood glucose result is below 50 mg/dL (or you see LO, less than 20 mg/dL) or is above 250 mg/dL (or you see HI, greater than 600 mg/dL) on the meter, please contact your healthcare professional as soon as possible.*
- *Please contact your healthcare professional if you decide to make a change to your current medical therapy based on test results.*

2. Blood β-Ketone Reference Ranges

The blood β-ketone test measures Beta-Hydroxybutyrate (β-OHB), the most important of the three ketone bodies in the blood.[2] The normal adult blood β-Ketone range for a person without diabetes is less than 0.6 mmol/L.[3] β-OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill.[2,4]

If your blood β-ketone result is 0.0 mmol/L and your blood glucose result is 300 mg/dL or higher, repeat both the ketone and the glucose tests 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 blood β-ketone result is between 0.6 and 1.5 mmol/L and your blood glucose result is 300 mg/dL or higher, this may indicate the development of a problem that could require medical assistance. Follow your healthcare professional's instructions.

If your blood β-ketone result is higher than 1.5 mmol/L and your blood glucose result is 300 mg/dL or higher, contact your healthcare professional promptly for advice and assistance. You may be at risk of developing diabetic ketoacidosis (DKA).[3-7]

References:

1. American Diabetes Association. Standards of Medical Care in Diabetes. Diabetes Care 2018; vol.41 (supplement 1): S13-S27.
2. Schade DS, Eaton RP. Metabolic and clinical significance of ketosis. Special Topics in Endocrinology and Metabolism 1982; 4: 1-27.
3. A. Rewers, Current Controversies in Treatment and Prevention of Diabetic Ketoacidosis, Advances in Pediatrics 57 (2010): 247-267
4. Harano Y, Kosugi K, Hyosu T, Suzuki M, Hidaka H, Kashiwagi A, Uno S, Shigeta Y. Ketone bodies as markers for Type 1 (insulin-dependent) diabetes and their value in the monitoring of diabetes control. Diabetologia 1984; 26: 343-348.
5. Ubukata E. Diurnal variation of blood beta-Ketone bodies in insulin-dependent diabetes mellitus and noninsulin-dependent diabetes mellitus patients: The relationship to serum C-Peptide immuno reactivity and free insulin. Ann Nutr Metab 1990; 34: 333-342.
6. Luzi L, Barrett EJ, Groop LC, Ferrannini E, DeFronzo RA. Metabolic effects of low-dose insulin therapy on glucose metabolism in diabetic ketoacidosis. Diabetes 1988; 37: 1470-1477.
7. Hale PJ, Crase J, Nattrass M. Metabolic effects of bicarbonate in the treatment of diabetes ketoacidosis. Br Med J 1984; 289: 1035-1038.

Questionable or Inconsistent Results

If your blood glucose or blood β-ketone result does not match how you feel, please:

- Check the expiration date and discard date of the test strip.
- Confirm the temperature in which you are testing is between 45.5 and 113°F.
- Make sure the test strip has been stored at 36-86°F, 10-90% relative humidity.
- Make sure the test strip was used immediately after removing it from the test strip foil pouch.
- Make sure that you followed the test procedure correctly.
- Perform a control solution test (See **Performing a Control Test** below for instructions).

After checking all of the conditions listed above, repeat the test with a new test strip. If you are still unsure of the problem, please contact **Keto-Mojo** at 800-513-1965 (5 days a week, 10am-4pm PST) for further assistance. Please contact your healthcare professional if you need help outside of these hours.

Testing with Control Solution

Why Perform Control Tests?

Performing a control test lets you know that your meter and test strips are working properly to provide reliable test results. You should perform a control test:

- Once a week
- When you open a new box of test strips
- When you want to check the meter and test strips
- When your test strips were stored in extreme temperature or humidity
- After cleaning your meter
- If you dropped the meter
- If you suspect your test result is not accurate. Or if your test result does not match with how you feel

About the Control Solutions

- Only use **Keto-Mojo®** Blood Glucose, and **Keto-Mojo®** Blood β-Ketone Control Solutions (2 and 3) to perform tests on this system.
- The control solution results are not included in the average value calculation.
- Store the control solution at 36-86°F, 10-90% relative humidity.
- All expiration dates are printed in Year-Month format. 2021-01 indicates January 2021.
- Do not use control solution that is out of the expiration date (the **Keto-Mojo®** Blood Glucose, **Keto-Mojo®** Blood β-Ketone control solution expires upon the expiration date or 6 months after the bottle is opened for the first time, whichever comes sooner.)
- Shake the bottle well before use.
- Close the bottle tightly after use.

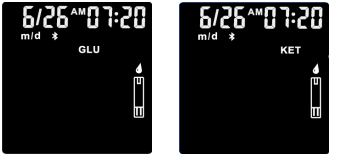
Performing a Control Test

1. Take out test strip from the test strip foil pouch.

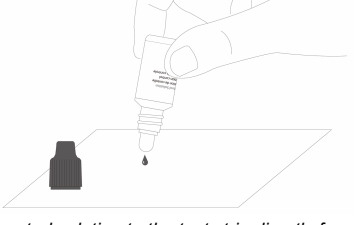
Note: *Check the expiration date of the test strips. Do not use expired test strips.*

2. Insert a test strip into the meter in the direction of the arrows.

3. The meter turns on after a beep. A symbol of a test strip with a flashing blood drop will appear letting you know the meter is ready to test.



4. Shake the control solution bottle thoroughly. Squeeze the control solution bottle gently and discard the first drop. Squeeze out a second small drop on a clean nonabsorbent surface.



Note: *Do not apply control solution to the test strip directly from the bottle.*

5. Immediately touch the tip of the test strip to the drop of control solution. The control solution is pulled into the test strip through the strip tip.

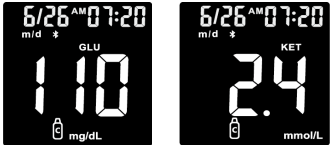
Note: *If the control solution sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.*

6. Hold it in the drop until the meter beeps and begins to count down on the screen, (from 5 seconds for glucose and from 9 seconds for ketones). Your control test result appears after a beep.

Note: *The meter will automatically recognize and show the control result for you. Control results are not included in the 7, 14 and 30-day average calculation.*

Understanding Your Control Test Result

Compare your control test result with the ranges printed on the test strip box or label.



GLU	mg/dL	KET	mmol/L
CTRL 2:	91 - 137	**CTRL 2:**	1.2-1.7
CTRL 3:	243 – 365	**CTRL 3:**	1.8-2.7

Notes:

If your control test result is out of range:

- *Check the expiration dates of the test strip and control solution. Make sure that the control solution bottle has not been opened for more than 6 months. Discard any expired test strips or control solution.*
- *Confirm the temperature in which you are testing the control solution is between 59-104°F.*
- *Make sure that you store the test strip and control solution at 36-86°F, 10-90% relative humidity.*
- *Make sure that the control solution bottle has been tightly capped.*
- *Make sure the test strip was used immediately after removing it from the test strip foil pouch.*
- *Make sure the control solution was mixed well.*
- *Confirm that you are using **Keto-Mojo®** blood glucose test strip and control solution, **Keto-Mojo®** blood β-ketone test strip and control solution.*
- *Make sure that you followed the test procedure correctly.*

After checking all of the conditions listed above, repeat the control solution test with a new test strip. If your results still fall out of the range indicated on the test strip box or label, your meter or test strips may not be working properly. **DO NOT** use the system to test blood. The system may not be working properly. If you cannot correct the problem, contact **Keto-Mojo** at 800-513-1965 (5 days a week,10am-4pm PST) for further assistance. Please contact your healthcare professional if you need help outside of these hours.

To turn your meter off, just take out the test strip. Dispose of the used test strips as medical waste. The result will be automatically marked and stored in the meter memory. Control results will not be included in your blood glucose averages.

Using the Meter Memory

Your meter automatically stores up to total 1000 results with the time and date. Test results are stored from the newest to the oldest. The meter will also calculate the average values of blood glucose records from the last 7, 14 and 30-days.

Notes:

- *If there are already 1000 records in memory, the oldest record will be erased to make room for a new one.*
- *It is very important to set the correct time and date in the meter, please make sure the time and date are correct after you change your battery.*

- *Control results of blood glucose are not included in your 7, 14 and 30-day average calculation.*

Viewing Your Test Results

When your meter is off, press the **power button** to turn the meter on. After a beep, a symbol of a strip flashes on the display. Press the **power button** again. Your last test result will display on the screen.

To view your 7, 14, and 30-day average blood glucose (averages are available only for glucose, not β-ketones), press the **top side button**; the 7-day average of blood glucose will appear in the center of the display.

Continue to press the **top side button** to view the 14-day average of blood glucose, then press the **top side button** again to review the 30-day average of blood glucose.

To view your previous readings (both glucose and β-ketones), press the **bottom side button**. Results will be shown starting with the most recent. Continue to press the **side button** to scroll through your readings.

When **END** appears on the display, you have viewed all the results in the memory.

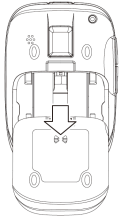
CHAPTER 4：MAINTENANCE AND TROUBLESHOOTING

Proper maintenance is recommended for best results.

Replace the AAA Batteries

When the meter AAA batteries need to be replaced, the battery symbol ( ) will appear, or you may receive an **E-11** error code.

1. Turn off your meter before changing the AAA batteries.
2. Press firmly on the battery cover and slide down.



Note: *After you change the AAA batteries, your meter prompts you to confirm the meter's time and date settings. All the test results are saved in the memory.*

3. Lift out and remove the old AAA batteries.
4. Place the new AAA batteries under the prongs and into the battery compartment.

5. Slide the battery cover back into place, lining up with the open slots, and close firmly.

Warning:

Keep batteries away from children. If swallowed, immediately contact your doctor or poison control center. Discard batteries according to your local environmental regulations.

Caring for Your Monitoring System

- Store meter in the carrying case provided whenever possible.
- Wash and dry hands well after handling to keep the meter and test strips free of water and other contaminants.
- **Keto-Mojo® GK+** Blood Glucose and β-Ketone Meter is a precision electronic instrument. Please handle it with care.
- Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt.

Cleaning and Disinfection

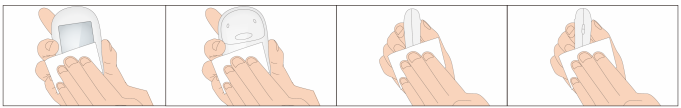
Your **Keto-Mojo® GK+** Blood Glucose and β-Ketone Meter should be cleaned and disinfected a minimum of once per week. Use only Clorox™ Healthcare Bleach Germicidal Wipes, which has been proven to be safe to use with the **Keto-Mojo® GK+** Blood Glucose and β-Ketone Meter.

Cleaning is part of your normal care and maintenance and should be performed prior to disinfection, but cleaning does not kill germs. After use and exposure to blood, all parts of this kit can potentially transmit infectious diseases. Disinfecting reduces the risk of transmitting infectious diseases.

Note: *If the meter is being operated by a second person who is providing testing assistance to you, the meter should be cleaned and disinfected prior to use by the second person.*

1. Cleaning Your Meter

Step 1: Take one piece of Clorox™ Healthcare Bleach Germicidal Wipes (EPA Registration No. 67619-12) from the container.
Step 2: Clean the entire meter surface including front side, back side, right side and left side.

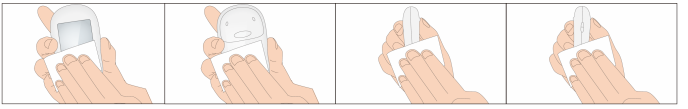


The meter should be cleaned when it is visibly dirty or at a minimum of once per week. This cleaning is to prepare the meter surface for a disinfection process.

2. Disinfecting Your Meter

Step 1: After cleaning your meter, take out a new piece of Clorox™ Healthcare Bleach Germicidal Wipes.

Step 2: Wipe the entire surface including front side, back side, right side and left side of the meter, with a back and forth movement.



Step 3: Keep the meter surface wet for at least one minute.
Step 4: Wait for the surface of meter to dry.

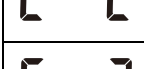
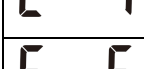
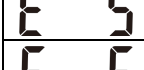
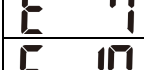
Clorox™ Healthcare Bleach Germicidal Wipes contain Sodium hypochlorite 0.55%, which has been proven to be safe to use with the **Keto-Mojo® GK+** Blood Glucose and β-Ketone Dual Monitoring System. Clorox™ Healthcare Germicidal Bleach Wipes are available by contacting Krasity's Medical Supply at 800-537-1394 directly or purchasing at http://www.walmart.com and http://www.staples.com/.
The meter should be disinfected a minimum of once per week. The meter disinfection process has been validated for 608 disinfection cycles, which is equivalent to cleaning and disinfecting your meter every 3 days for 5 years. This is to ensure that your meter will operate properly over the 5-year life of the meter.

Note:
- *Do not use alcohol or any other solvent.*
- *Do not allow liquid, dirt, dust, blood, or control solution to enter the test strip port or the data port.*
- *Do not squeeze or wipe gauze into the test strip port.*
- *Do not spray cleaning solution on the meter.*
- *Do not immerse the meter in any liquid.*

Note: *Although it has not been observed, some alterations may appear on your meter due to the cleaning and disinfection procedure. Items such as: cloudy display window, plastic housing cracking, meter buttons that do not function, partial display on full screen, unable to execute the meter's initial set up, etc. may appear. If you notice any of these external changes to your meter or any changes to the performance of your meter stop using the meter and please contact* ***Keto-Mojo*** *at 800-513-1965 (5 days a week,10am-4pm PST) for further assistance. Please contact your healthcare professional if you need help outside of these hours.*

If you have questions about cleaning or disinfection, or if you see evidence of physical damage, please contact **Keto-Mojo** at 800-513-1965 (5 days a week, 10am-4pm PST) for further assistance. Please contact your healthcare professional if you need help outside of these hours.

Troubleshooting Guide

What You See	What It Means	What You Should Do
	Blood or control solution was added before the flashing blood drop appears.	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
	The meter is sensing a used or contaminated test strip.	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing. Never put blood on the strip before inserting it into the meter.
	Incorrect test strip.	Discard the test strip and repeat the test with a new test strip. Make sure that you are using **Keto-Mojo®** Blood Glucose or **Keto-Mojo®** Blood β-Ketone Test Strips.
	Incorrect sample.	Discard the test strip and repeat the test with a new test strip. Make sure that you are using a blood sample or **Keto-Mojo®** Blood Glucose, **Keto-Mojo®** Blood β-Ketone Control Solution.
	Temperature out of range.	Move to an area that is within the operating range for the meter. Let the meter adjust to this temperature for 20 minutes before testing.
	Potential hardware issue.	Take the batteries out and restart the meter. If the problem continues, contact **Keto-Mojo** at 800-513-1965 (5 days a week, 10am-4pm PST) for further assistance. Please contact your health care professional if you need help outside of these hours.
	Insufficient sample.	Discard the test strip, repeat the test with a new test strip and apply enough sample to fill check window of the test strip.
	Low Battery Indicator	Replace batteries and check date/time/year settings.
	Blood glucose test result is above 600 mg/dL; blood β-ketone test result is above 8.0 mmol/L.	Wash and dry your hands and the test site well, then repeat the test using a new test strip. If your result still flashes HI, contact your healthcare professional as soon as possible.
	Blood glucose test result is below 20 mg/dL; blood β-ketone test result is below 0.1 mmol/L.	Wash and dry your hands and the test site well, then repeat the test using a new test strip. If your blood glucose result still flashes LO, contact your healthcare professional as soon as possible.

Symptoms of High/Low Blood Glucose and Ketoacidosis

You can better understand your test results by being aware of the symptoms of high/low blood glucose and ketoacidosis. According to the American Diabetes Association, some of the most common symptoms are:

Low blood glucose (Hypoglycemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- irritability
- seizure
- extreme hunger
- dizziness

High blood glucose (Hyperglycemia):

- frequent urination
- excessive thirst
- blurred vision
- increased fatigue
- hunger

Ketones (ketoacidosis):

- shortness of breath
- nausea or vomiting
- very dry mouth

Warning:

If you are experiencing any of these symptoms, test your blood glucose / β-ketone. If your test result does not match with how you feel, contact your healthcare professional immediately.

CHAPTER 5: TECHNICAL INFORMATION

System Specifications

Feature	Specification
Measurement Range	Blood glucose: 20-600 mg/dL; Blood β-ketone: 0.1-8.0 mmol/L
Test Measured	Blood Glucose/β-Ketone in fingertip capillary whole blood
Sample	Fresh capillary whole blood
Sample Volume	Blood glucose: 0.8 μL; Blood β-ketone: 0.8 μL
Test Time	Blood glucose: 5 seconds; Blood β-ketone: 9 seconds
Power Source	Two AAA LR03 1.5V batteries
Battery Life	12 months or approximately 1,000 tests
Units of Measure	Blood glucose: Milligrams per deciliter (mg/dL); Blood β-ketone: Millimoles per liter (mmol/L)
Memory	Up to 1000 records
Automatic Shutoff	2 minutes after last action
Dimensions	90.7 mm x 60.3 mm x 25.1 mm
Weight	Approximately 63g
Operating Temperature	45.5-113°F
Operating Relative Humidity	10-90%
Hematocrit Range	Blood glucose: 20-70%; Blood β-ketone: 20-65%
Bluetooth	Bluetooth Low Energy (BLE)

Clinical Study for Blood Glucose

The **Keto-Mojo® GK+** Blood Glucose and β-Ketone Dual Monitoring System was tested by 352 lay users using capillary blood samples and three **Keto-Mojo®** Blood Glucose test strip lots. The results were compared to the YSI Model 2300 STAT PLUS Glucose Analyzer, a laboratory instrument. The tables below show how well the two methods compared.

Table 1-Linear Regression Results

Slope	0.9960
Y-Intercept	-0.2740 mg/dL
Correlation coefficient (R)	0.9974
Number of sample	352
Range tested	38.6-548.9 mg/dL

Table 2-Consumers Accuracy Results

The numbers and percentages represented in this table are the number of meter results compared to a laboratory result.

Difference range between the true blood glucose level and the **Keto-Mojo® GK+** Blood Glucose and β-Ketone meter result.	Within ±5%	Within ±10%	Within ±15%	Within ±20%
The percent (and number) of meter results that match true blood glucose level within x%	61.6% (217/352)	95.5% (336/352)	100% (352/352)	100% (352/352)

Accurate Results (Meter result is +/-15% of laboratory result)	352 out of 352 (100% of results)
More Accurate Results (Meter result is +/-10% of laboratory result)	336 out of 352 (95.5% of results)
Most Accurate Results (Meter result is +/-5% of laboratory result)	217 out of 352 (61.6% of results)

Clinical Study for Blood β-Ketone

The **Keto-Mojo® GK+** Blood Glucose and β-Ketone Dual Monitoring System was tested by 102 lay persons using capillary blood samples and three **Keto-Mojo®** Blood β-Ketone test strip lots. The results were compared to the Randox RX Imola Chemistry Analyzer. The tables below show how well the two methods compared.

Table 1-Linear Regression Results

Slope	1.0037
Y-Intercept	-0.0083 mmol/L
Correlation coefficient(R)	0.9927
Number of sample	102
Range tested	0.11-1.52 mmol/L

Table 2-Consumers Accuracy Results

The numbers and percentages represented in this table are the number of meter results compared to a laboratory result.

For Blood β-Ketone Concentration <1.5 mmol/L			
Difference range between the true blood β-ketone level and the **Keto-Mojo® GK+** Blood Glucose and β-Ketone meter result.	Within ±0.1 mmol/L	Within ±0.2 mmol/L	Within ±0.3 mmol/L
The percent (and number) of meter results that match true blood β-ketone level within x%	100% (101/101)	100% (101/101)	100% (101/101)

Accuracy Results for Blood β-Ketone Concentration <1.5 mmol/L	
Accurate Results (Meter result is +/-0.3 mmol/L of laboratory result)	101 out of 101 (100% of results)
Accurate Results (Meter result is +/-0.2 mmol/L of laboratory result)	101 out of 101 (100% of results)
Accurate Results (Meter result is +/-0.1 mmol/L of laboratory result)	101 out of 101 (100% of results)

Remarks: 1/1 sample with concentration ≥ 1.5 mmol/L measured and found within ± 5% of laboratory comparator.

Warranty

Please register your meter for warranty online at Keto-Mojo.com

***Note*:**

This warranty applies only to the meter in the original purchase and does not apply to the AAA batteries supplied with the meter.