

Dear KetoCoach™ Owner aka Awesome Person

You did it! You're making an effort to improve your health through measuring ketones. You're awesome. And we're honored to be along for the journey.

First of all, thank you for choosing the KetoCoach™ Blood Ketone Monitoring System to help you accurately monitor your blood ketone level. Your new KetoCoach™ Blood Ketone Monitoring System is an autocoding system that does not require you to manually select the correct calibration (commonly known as "coding the meter"). Pretty cool! All of the information you need to use and maintain the KetoCoach™ Blood Ketone Monitoring System is included in this manual. Before you begin using your new KetoCoach™ Blood Ketone Monitoring System, please read all of the instructions provided in this User's Manual, then follow the instructions in test strips package insert.

For questions or support, please visit our website at www.ketocoachx.com or call 1-800-587-5496. We're here to help you have a great experience with our product.

Intended Use

The KetoCoach™ Blood Ketone Monitoring System is intended to quantitatively measure β -hydroxybutyrate (β -ketone) in fresh capillary whole blood from fingertips. It should only be used by a single patient and it should not be shared. Testing is done outside the body (In Vitro diagnostic use). It is intended for self-testing by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control programs. It is not to be used for diagnosis or screening of diabetes, or for neonatal use.

The KetoCoach™ Blood Ketone Monitoring System is comprised of the KetoCoach™ Blood Ketone Meter and KetoCoach™ Blood Ketone Test Strip and KetoCoach™ Ketone Control Solution.

IMPORTANT:

- Dehydration – Severe dehydration may lead to inaccurate blood ketone test result. If you suspect you are severely dehydrated, contact your healthcare professional immediately.
- A hematocrit range that is higher than 60% or lower than 20% can cause inaccurate blood ketone test results.
- Suitable for self-testing.
- Not intended for use on neonates.

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 biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

The link of public health notifications and standard practice guidelines are :

- “FDA Public Health Notification: Use of Fingerstick 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 Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010) <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

Limitations

1. The system should not be used to test neonates.
2. Do not test samples other than fresh capillary whole blood obtained from the fingertip.

3. Do not use the system at altitudes above 10,335 feet (3,150meters).
4. Do not use when Hematocrit is outside the acceptable hematocrit range for testing of 20% to 60%.
5. Severe dehydration (excessive water loss) may cause inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
6. For in vitro diagnostic use only.
7. Critically ill patients should not be tested with this device.
8. Inaccurate results may occur in severely hypotensive individuals or patients in shock or in a hyperglycemic-hyperosmolar state.
9. Incorrect result may occur in individuals who are dehydrated.
10. The meter and lancing device are for single patient use. Do not share these items with anyone, including other family members! Do not use on multiple patients!
11. Do not reuse; each test strip is for single use only.
12. Do not use when humidity is higher than 90% and lower than 20%, as extremes in humidity may affect results.
13. For single patient use only.
14. For over-the counter use.
15. The system is not intended for use in the diagnosis of or screening for diabetes mellitus.

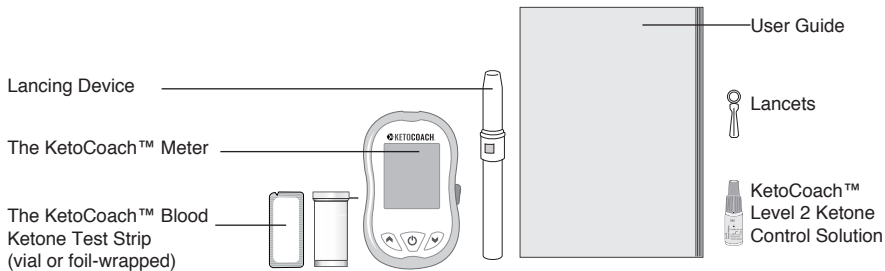
Table of Contents

Understanding Your KetoCoach™ Blood Ketone Monitoring System.	7
The KetoCoach™ Meter	8
The KetoCoach™ Meter Display Screen	10
The KetoCoach™ Blood Ketone Test Strip	12
Setting Up Your New System	13
Inserting (or Changing) the Battery	13
Setting the Clock	15
Setting the Alarm	19
Turning ON/OFF Tone Sound	21
Control Solution Testing.	24
Performing a Ketone Control Solution Test	24
Control Solution Troubleshooting.	30
Testing your Blood Ketones.	31
Preparing Your Lancing Device	32
Performing a Blood Ketone Test	34

Understanding Your Test Results	38
Understanding Your Blood Ketone Test Results	38
Viewing Stored Readings from Memory	40
Viewing Stored Readings of Ketone Test Results from Memory	40
Caring for the Meter	43
Cleaning the Meter	43
Storage and Precautions	48
Solving Problems	50
Product Warranty	54
Specifications	55
Supplies	56

Understanding Your KetoCoach™ Blood Ketone Monitoring System

Each KetoCoach™ system may include the following items:

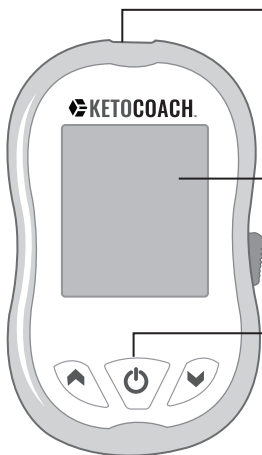


Note:

- Contents may change without notice.
- Lancets and Lancing Device are optional components.
- KetoCoach™ Blood Ketone Test Strip, KetoCoach™ Ketone Control Solution are necessary but sold separately.

Please contact us at www.ketocoachx.com for purchasing information.

The KetoCoach™ Meter



Test Strip Port

This is where you insert the test strip and the meter will turn on automatically.

Meter Display

Show your test results, memory values, average, and other messages.

Enter (⏻) and ▲▼ buttons

Press and hold (⏻) for 2 seconds to turn the meter on or off, or press (⏻) to go into setup mode when not testing.

Press ▲ or ▼ to enter control mode with test strip inserted, during meter setup, or to navigate the stored test values and averages.

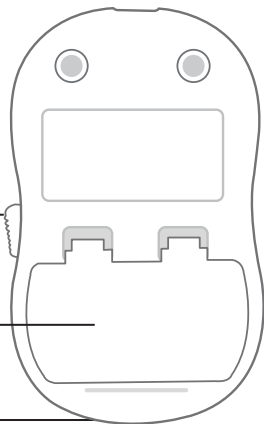
Ejection Switch

Push and eject a used test strip. Meter will turn off automatically when the test strip is ejected.

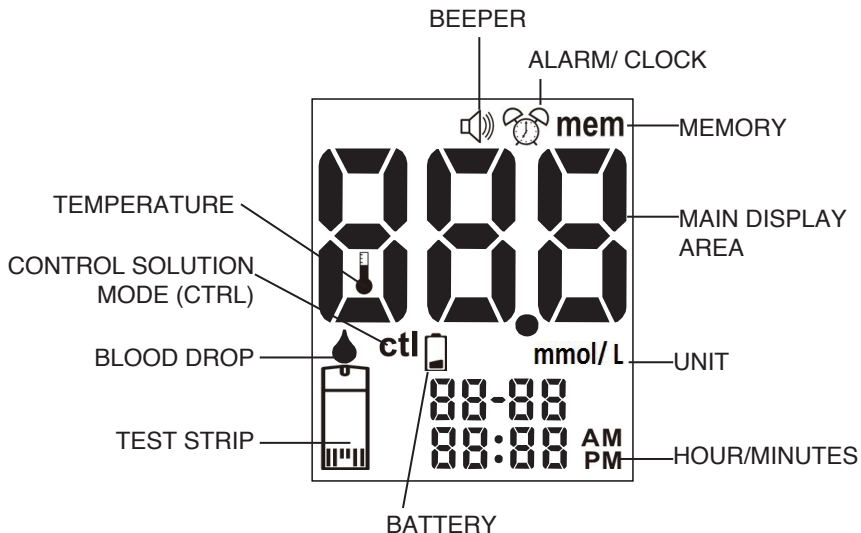
Battery Compartment

Holds two CR 2032 3V Lithium coin cell batteries.

The USB is not active in this meter.



The KetoCoach™ Meter Display Screen



- MAIN DISPLAY AREA.....Displays test results, stored test values, calculated result averages, and messages
- MEMORYIndicates the number in the main display area is a stored test value (see page 40)
- BATTERYAppears when the battery is low and needs to be replaced
- TEMPERATUREAppears when it is either too hot or too cold to test (outside the ranges 50°F~104°F for ketone test)
- TEST STRIPThis icon will flash to prompt you to insert a test strip for testing
- UNITUnit of measurement for your blood ketones
- CTRLIndicates a control solution test (see page 24)
- BEEPER.....Appears when turning ON/OFF tone sound (see page 20)
- ALARMIndicates the alarm function is on (see page 19)
- CLOCKAppears when setting date and time (see page 15)
- BLOOD DROP.....This icon will flash to indicate the meter is ready for testing

The KetoCoach™ Blood Ketone Test Strip

Contact Points

Insert this end to the test strip port on the meter



Sampling End

Apply blood or control solution here


The KetoCoach™ Blood Ketone Test Strip is ketone specific, biosensor-based test strip that can test blood ketone levels in capillary whole blood in as quickly as 8 seconds and requires very little blood sample. The test result is plasma referenced for easy comparison to lab results and has under-fill detection to alert you when there is not enough blood to perform a test, so you can be assured that each reading you get is an accurate and meaningful result when the control reading is within the specified range.

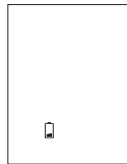
IMPORTANT:

- Be sure to use only the KetoCoach™ Blood Ketone Test Strip with the KetoCoach™ Meter. Other brands of test strips will not work with the meter.
- The KetoCoach™ Blood Ketone Test Strip is sensitive to moisture and light. For vial test strips, it is important to close the vial cap of the test strip bottle tightly after each use. DO NOT leave any test strips outside the bottle while not in use.
- Carefully discard used test strips and lancets in proper waste containers according to your healthcare provider's instructions.
- DO NOT reuse test strip. The test strip is for single use only.

Setting Up Your New System

Inserting (or Changing) the Battery

The batteries need to be inserted before using your KetoCoach™ Meter for the first time or when the “” icon appears on the meter display screen.

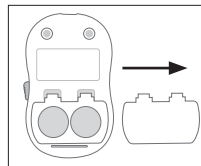


Material you will need:

- Two CR 2032 3V Lithium coin cell batteries
- Your KetoCoach™ Meter

Step 1.

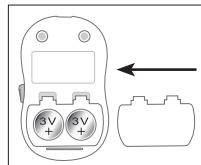
Turn meter off. Remove the battery cover on the back of the meter by pushing the tab and pulling the door up. Remove the old batteries.



Step 2.

Insert the new batteries with the + side up. They do not snap into place but rest on the metal contact. The door holds the batteries down.

Put the battery door back in place and snap it closed.



NOTE:

- After changing the batteries, the meter automatically prompts you to check the time and date when it is turned on either by inserting a test strip or pressing “⏻”. If it is correct, press “⏻” to confirm setup and exit, or if the time and date are not correct, turn to page 15 for Setting the Clock.
- The date and stored results will not be erased when the batteries are being changed.
- Discard used batteries according to your local regulation.
- The meter uses two 3-volt lithium batteries, coin cell CR2032. This type of battery can be found in many stores. Always keep a spare packaged battery on hand.
- Be sure the batteries go in + side up.
- Remove the batteries if unused for a long time.

Setting the Clock

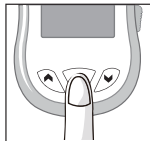
Material you will need:

- Your KetoCoach™ Meter

Begin Set Up

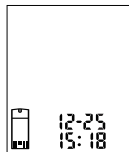
Step 1.

Press and hold “” to turn on the meter.



Step 2.

The flashing test strip icon will appear on the meter display screen.



Step 3.

Press “” twice and the meter display screen shows “”.

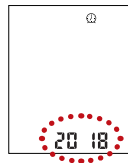


Set Year

Step 4.

Press “⏏” and the current year will flash. Use “▲” or “▼” to select the correct year.

Press “⏏” to confirm your choice and advance to set the month.

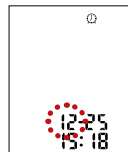


Set Month

Step 5.

The current month will flash. Use “▲” or “▼” to select the correct month.

Press “⏏” to confirm your choice and advance to set the day.

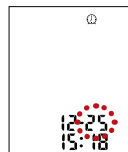


Set Day

Step 6.

The current day will flash. Use “▲” or “▼” to select the correct day.

Press “⏏” to confirm your choice and advance to set the 12-hour or 24-hour time format.

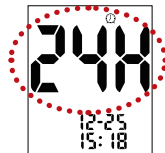


Set 12-hour or 24-hour Time Format

Step 7.

The time format will flash. Use “▲” or “▼” to select the time format of your choice.

Press “⏻” to confirm your choice and advance to set the hour.

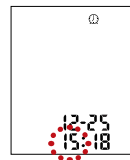


Set Hour

Step 8.

The current hour will flash. Use “▲” or “▼” to select the correct hour.

Press “⏻” to confirm your choice and advance to set the minutes.

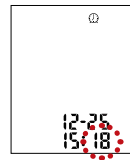


Set Minutes

Step 9.

The current minutes will flash. Use “▲” or “▼” to select the correct minutes.

Press “⏻” to confirm your choice and exit time setup.



NOTE:

- Anytime during setup, you may either press “⏻” to exit, or insert a KetoCoach™ Blood Ketone Test Strip to begin testing. The changes you have done so far will be memorized by the meter.

After setting up your clock, you can turn off the meter by holding and pressing “⏻”, continue to set your meter, or insert a test strip to begin testing (see Testing Your Blood Ketone on page 31, or Control Solution Testing on page 24).

Setting the Alarm

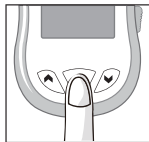
You can set up to three alarms for ketone testing on your KetoCoach™ Meter. You must set the clock before setting the alarms. When an alarm rings, a melody will play for 20 seconds. Pressing “⏻” or inserting a test strip will silence the alarm.

Materials you need:

- Your KetoCoach™ Meter

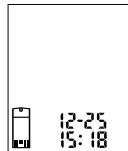
Step 1.

Press and hold “⏻” to turn on the meter.



Step 2.

The flashing test strip icon will appear on the meter display screen.



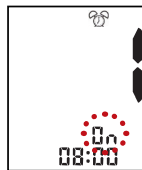
Step 3.

Press “▲” or “▼” until “🕒” starts to flash. Press “⏻” to enter alarm setting.



Step 4.

The display screen will indicate alarm 1 status (the default is OFF). You can turn it on by pressing “▲” or “▼”. Press “⏻” to confirm your choice and advance to set the hours.



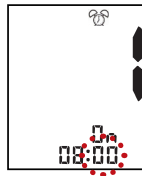
Step 5.

The hours will flash. Press “▲” or “▼” to select the hour. Press “⏻” to confirm your choice and advance to set the minutes.



Step 6.

The minutes will flash. Press “▲” or “▼” to select the correct minutes. Press “⏻” to confirm your choice and advance to set alarm 2.



Step 7.

Set alarm 2 and 3 by following steps 4 through 6. After you have finished setting up alarm 3, press “⏻” to exit alarm setup.



NOTE:


- Alarm will follow the time format (12-hour or 24-hour) you chose when setting up the clock.
- Alarm settings will not be erased when changing batteries.

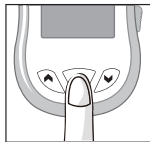
Begin testing by inserting a test strip (see Testing Your Blood Ketone on page 31 or Control Solution Testing on page 24), or press and hold “⏻” to turn off the meter.

Turning ON/OFF Tone Sound

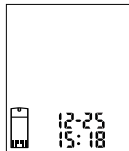
The KetoCoach™ Meter comes with beeper sound ON as preset. Turning off the beeper will cause you to miss many important cues from your meter – such as confirmation or error messages.


Step 1.

Press and hold “” to turn on the meter.

**Step 2.**

The flashing test strip icon will appear on the meter display screen.

**Step 3.**

Press “” or “” until meter display screen shows “”.

**Step 4.**

Press “” to enter tone setting. Use “” or “” to turn on/off the tone.

**Step 5.**

Press “” to confirm and exit once you have made your selection.

NOTE:

- Anytime during setup, you may either press “⏻” to exit, or insert a test strip to begin testing. The changes you have done so far will be memorized by the meter.

Begin testing by inserting a test strip (see Testing Your Blood Ketone on page 31 or Control Solution Testing on page 24), or press and hold “⏻” to turn off the meter.

Control Solution Testing

Performing a Ketone Control Solution Test

The purpose of the ketone control solution testing is to validate the performance of the KetoCoach™ Blood Ketone Monitoring System using the testing solution with a known range of ketone. The control solution is necessary for the ketone control solution test but is sold separately. Please contact us at www.ketocoachx.com for purchasing information.

You should perform control solution testing when:

- Using the meter for the first time
- You open a new bottle of KetoCoach™ Blood Ketone Test Strips
- You leave the cap of the test strip vial open for a while
- You drop the meter
- You suspect your KetoCoach™ Meter and KetoCoach™ Blood Ketone Test Strip are not working properly
- You want to practice the testing procedure

IMPORTANT:

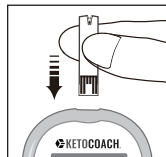
- Use only the KetoCoach™ Ketone Control Solution (Level 2) with the KetoCoach™ Blood Ketone Test Strip. Other brands of control solution will produce inaccurate results.
- Always check the expiration date. DO NOT use control solutions if expired.
- Mark the newly opened bottle of control solution with the date opened. Discard any unused control solution three months after opening.
- DO NOT FREEZE or REFRIGERATE. Store the control solutions at 39°F ~86°F and 10% ~ 85% RH.

Materials you will need:

- KetoCoach™ Ketone Control Solution (Level 2)
- Your KetoCoach™ Meter
- A new KetoCoach™ Blood Ketone Test Strip

Step 1.

Insert a KetoCoach™ Blood Ketone Test Strip into the meter with the blood sample reaction zone facing up. Make sure the test strip contact points are inserted all the way into the meter.

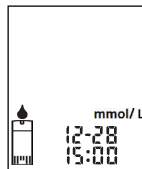


IMPORTANT:

- Do not use a test strip that has expired. Check the expiration date which is printed on the test strip bottle (for vial test strip) or box (for foil-wrapped test strip).
- Use each test strip immediately after removing it from the bottle.
- For vial test strip, replace the bottle cap immediately and close it tightly after removing a test strip from the bottle.
- Do not use wet or damaged test strips.
- Keep away from direct sunlight and heat. Store the test strip in a dry, cool place.
- For vial test strip, record the “date opened” on the test strip bottle label when you first open it. Three months after first opened, discard the bottle and any remaining test strips.
- For foil-wrapped test strip, do not use scissors to open the foil wrapping. Scissors can damage test strips.
- Make sure you are testing in an environment between 50°F~104°F and relative humidity between 10% ~ 85%, and allow 10 to 15 minutes for it to reach the new temperature before use. Your meter will not begin testing if it detects an out-of-range temperature.
- This is an auto-coding meter. You do not need to insert a code card.
- The flashing blood drop icon must be displayed if the test strip has been properly inserted into the test strips port.

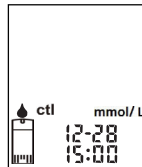
Step 2.

The flashing blood drop and test strip icons appear on the lower left of the meter display screen.



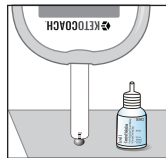
Step 3.

Press “▲” or “▼” to enter the control mode. You will see “ctl” on the lower left of the screen .



Step 4.

Squeeze a drop of ketone control solution (Level 2) onto a clean, dry, non-absorbent surface. Do not apply control solution to the test strip directly from the bottle. Replace the bottle cap on the control solution bottle immediately after use.

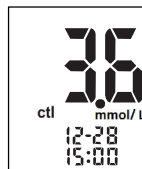


Step 5.

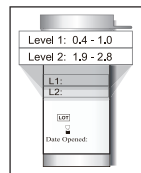
Hold the meter and touch the control solution to the edge of the sampling end of the test strip. The control solution will be automatically pulled into the reaction area of the test strip.

Step 6.

The screen will begin to count down. After 8 seconds, the control solution testing result will appear on the meter display screen. A “ctl” flag will also be attached when results are shown on the screen.

**Step 7.**

Compare the reading on the screen to the control range printed on the test strip bottle (for vial test strip) or box (for foil-wrapped test strip). If the reading does not fall within the control range printed on the test strip bottle or its package, see Control Solution Trouble Shooting on page 30.

**NOTE:**

- Control solution testing results will be stored into the meter's memory and indicated by “ctl” icon.
- Replace the bottle cap on the control solution bottle immediately after use.

Step 8.

Remove the used test strip either by pushing the ejection switch or by pulling it out with your hand and throw it into a proper wastebasket, the meter will turn off automatically. The meter will also time-out after 1.5 minutes of inactivity.

IMPORTANT:

- Do not reuse test strips.
- Used test strips are biohazard materials and can transmit blood-borne disease. Please follow your local healthcare provider's recommendation regarding proper disposal of used test strips.

Perform other level of control solution testing by repeating the above steps.

Control Solution Troubleshooting

If your control solution testing is out of range (too high or too low), it may be caused by the following:

Possible Causes

- Wrong brand of control solution being used
- Expired or contaminated control solution or damaged test strips
- Meter malfunction
- Control solution not at right storage temperature

What you can do ...

- Make sure you are using KetoCoach™ Ketone Control Solution (Level 2).
- Make sure the testing environment is between 10°C~40°C (50°F ~104°F) and relative humidity 10% ~85%.
- Check the expiration and opened date on bottles of both control solution and test strip. Repeat the test using a new test strip. If the result is still out of range, use a new bottle of control solution and retest.
- Please contact us at www.ketocoachx.com for questions and inquiries.

Testing Your Blood Ketones

Materials you will need:

- Your KetoCoach™ Meter
- A new KetoCoach™ Blood Ketone Test Strip
- Lancing device with a sterile, unused lancet

Before you begin, make sure:

- You set up your meter properly and run a control test. See Setting Up Your New System on page 13 and Perform a Ketone Control Solution Test on page 24 for more details.
- You wash your hands and testing site thoroughly with soap and warm water, and dry well.
- You are testing in an area between the temperature ranges of 10°C~40°C (50°F ~104°F) and relative humidity 10% ~ 85%. Your meter will not test outside of this range and will display "🌡️". Move the meter into an area that is between 10°C~40°C (50°F ~104°F) and 10% ~ 85% RH, and let it sit for 10 to 15 minutes before testing again.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected appropriately when testing is conducted by the second person.

Preparing Your Lancing Device

CAUTION:

- The lancets are for single use only. Always use a new, sterile lancet each time you perform the test.
- DO NOT share your lancing device or lancets with other people. Sharing or reusing lancets can lead to disease transmission.
- Dispose properly in biohazard waste.
- When performing a blood ketone test, use a new sterile lancet every time. If alcoholic wipes are used to cleanse the fingers, make sure the area is dry before the blood sample is obtained.

Step 1.

Wash the puncture site with soap and warm water and dry thoroughly. Warm water stimulates blood flow making it easier to obtain a sample.

Step 2.

Hang the arm down at the side for 10 to 15 seconds massaging through the wrist, palm, and then finger. This can stimulate the blood flow more quickly.

Step 3.

Hold the lancing device (puncture) or lancet against the puncture site and lance it. Follow manufacturer's instruction for how the lancing device (puncture) or lancet should be used.

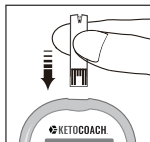
TIP:

- To avoid soreness, select a site on the side of your fingertips. To avoid calluses, choose a different site each time for obtaining the blood sample.

Performing a Blood Ketone Test

Step 1.

Insert a KetoCoach™ Blood Ketone Test Strip to turn on the meter.

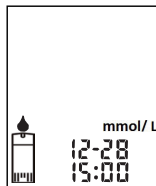


IMPORTANT:

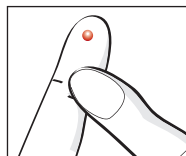
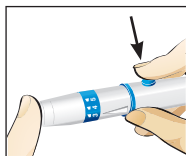
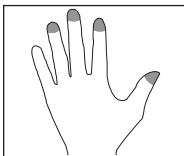
- Check the expiration date printed on the test strip bottle (for vial test strip) or box (for foil-wrapped test strip). Do not use expired test strips.
- Use each test strip immediately after removing it from the bottle or opening a foil wrapping.
- Do not use wet or damaged test strips.
- Keep away from direct sunlight and heat. Store the test strip in a dry, cool place.
- For vial test strip, record the “date opened” on the bottle label. Discard the bottle and any remaining test strip after three months from date of opening.
- For foil-wrapped test strip, do not use scissors to open the foil wrapping. Scissors can damage test strips.
- Insufficient blood specimen may cause incorrect results.
- Must see a flashing blood drop icon if the test strip has been inserted to the test strip port.

Step 2.

Wait for the flashing blood drop and test strip icons to appear on the left of the meter display screen.

**Step 3.**

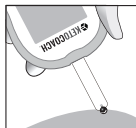
Hold the lancing device against the side of your fingertip and press the release button to create a puncture.

**TIP:**

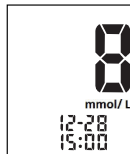
- Gently massage your hand and finger toward the puncture site to form a drop of blood (approximately●). Do not “milk” or squeeze around the puncture site.
- Lance the side of your fingertip to avoid soreness. To avoid calluses, choose a different lancing site each time.

Step 4.

Gently bring the test strip and touch the drop of blood at a slight angle. The test strip acts like a straw to pull the blood in. Keep the test strip in the blood drop until the meter beeps to indicate the test strip has enough blood to test.

**Step 5.**

The screen will start to count down. After 8 seconds, your ketone testing result will appear on the meter display screen.

**NOTE:**

- If error messages (Err1, Err2, *etc.*) appear, see Solving Problems on page 45.
- The meter will turn off automatically when you pull the test strip out or after 1.5 minutes of inactivity.

Step 6.

Remove the used test strip either by pushing the ejection switch or by pulling it out with your hand and throw it into a proper wastebasket and the meter will turn off automatically. The meter will also time-out after 1.5 minutes of inactivity.

Step 7.

Remove the used lancet from your lancing device according to instructions and discard it into a proper wastebasket.

CAUTION:

- If you see “HI” or “LO” is displayed, your blood ketone level may be beyond the meter measurement range (above 8.0 mmol/L or below 0.1 mmol/L). Test again using fingertip testing. If you still receive the same result, call your physician or healthcare professional immediately.
- If you get result of “HI” or “LO”, it will be stored as 8.0 mmol/L or 0.1 mmol/L in meter’s memory automatically.

IMPORTANT:

- Used lancets and strips are biohazard materials and can transmit blood-borne disease. Please follow your local healthcare provider's recommendation regarding proper disposal of used lancets.
- Clean and disinfect the meter and lancing device after the test. Refer to *Cleaning and Disinfecting Your Meter and Lancing Device* on page 43.
- Wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

Understanding Your Test Results

Understanding Your Blood Ketone Test Results

Ketones are made when the body is using fat for energy instead of using glucose because not enough insulin is available to use glucose for energy. It is a warning sign that your diabetes is out of control or that you are getting sick ⁽¹⁾.

The normal adult blood β -Ketone range for a person without diabetes is less than 0.6 mmol/L. If level increases, it might represent ⁽²⁾:

- 0.6 to 1.5 mmol/L..... a moderate level of ketones and probably indicates fat metabolism and weight loss, but not a deficiency of insulin, test again later and contact your healthcare professional for advice
- 1.6 to 3.0 mmol/L..... a high level of ketones and under a risk of diabetes ketoacidosis (DKA), contact your healthcare professional immediately
- Above 3.0 mmol/L.... a serious metabolic condition and emergency medical care is necessary

What to do if you get a high reading

If the meter displays results that are “HI”:

- Treat your diabetes according to the instructions from your doctor and/or consult with your healthcare provider.
- Test your meter with a control solution, refer to Control Solution Testing on page 24.
- Test again with a new test strip. If you still get a high reading, contact your healthcare professional immediately.

IMPORTANT:

- Inaccurate results may occur for individuals experiencing severely hypotensive, severely dehydrated, in shock, or in a hyperglycemic-hyperosmolar state.

1. *DKA (Ketoacidosis) & Ketones*, <http://www.diabetes.org/living-with-diabetes/complications/ketoacidosis-dka.html>, March 18, 2015
2. A. Rewers, *Current Controversies in Treatment and Prevention of Diabetic Ketoacidosis*, *Advances in Pediatrics* 57 (2010) 247–267.

Viewing Stored Readings from Memory


Viewing Stored Readings of Ketone Test Results from Memory

Your KetoCoach™ Meter can store up to 500 ketone test and control results with date and time. You will need to set your meter date and time before using the memory, see Setting Up Your New System on page 13. The meter will not memorize any test or control results if the date and time are not set.

Material you will need:

- Your KetoCoach™ Meter




Step 1.

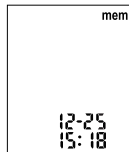
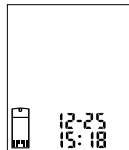
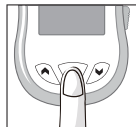
Press and hold “” to turn on the meter.

Step 2.

The flashing test strip icon will appear on the meter display screen.

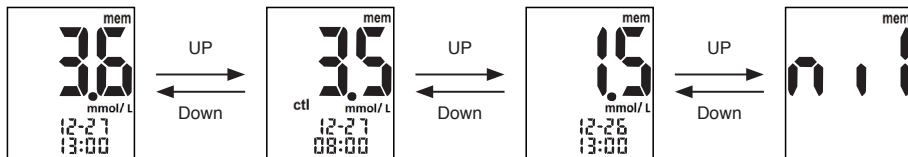
Step 3.

Use “” or “” until meter display screen shows “**mem**”, press “” to confirm your choice

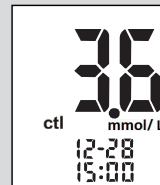


Step 4.

The most recent test result will appear on screen. Press “▲” to view your results from the most recent to the oldest. When scrolling to the end of results in the memory, the display screen will show “nil”.

**NOTE:**

- Control testing results will be flagged by a “ctl” icon on lower left of the unit measurement.
- When the memory is full, performing a new test will delete the oldest test result.
- If you get result of “HI” or “LO”, it will be stored in memory as 8.0 mmol/L or 0.1 mmol/L.



After you finish viewing memory, either begin testing by inserting a test strip (see Testing Your Blood Ketone on page 31, or Control Solution Testing on page 24), or press and hold “⏻” to turn off the meter.

Caring for the Meter

Caring for your KetoCoach™ Meter is easy. Follow these simple guidelines to keep your KetoCoach™ Meter working properly.

NOTE:

- Do not get water inside the KetoCoach™ Meter. Never immerse the meter or hold it under running water.
- Do not use glass or household cleaners on the meter.
- Do not try to clean the test strip holder.
- Do not contaminate the strip holder with blood or control solution.
- Handle the meter with care; severe shock, such as dropping the meter, could damage the electronics.

Cleaning and Disinfecting Your Meter and Lancing Device

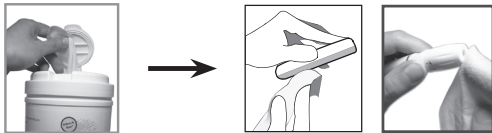
Cleaning and disinfecting your meter and lancing device are very important in the prevention of infectious disease. Cleaning is the removal of dust and dirt from the meter and lancing device surface so no dust or dirt gets inside. A cleaning step using a Clorox Healthcare Bleach Germicidal wipe must be performed before each disinfection step. Disinfection is the removal of bloodborne pathogens that is the way to reduce your exposure to disease.

Your meter and lancing device is validated to withstand cleaning and disinfection cycle of once per day for an average period of five years (1825 cleaning cycles and 1825 disinfection cycles over the 5 year use life of the meter) using Clorox Healthcare Bleach Germicidal Wipes (EPA Registration Number: 67619-12). Clorox Healthcare Bleach Germicidal Wipes is available through major retailers online, please refer to page 46 for purchase information.

We recommend cleaning and disinfecting your device once a week.

1. Wash hands with soap and water and dry thoroughly.
2. Inspect for blood, debris, dust, or lint anywhere on the meter or lancing device.
3. To clean the meter or lancing device, use Clorox Healthcare Bleach Germicidal Wipe.

Wipe all external areas of the meter or lancing device including both front and back surfaces until visibly clean at a minimum wipe all surfaces with 3 vertical and 3 horizontal wipes. Discard used towel in a sealed container where it will not be touched by others.



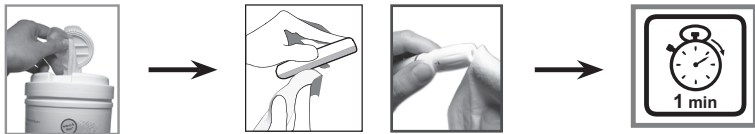
NOTE:

- If towelettes seem very dry, invert the canister once or twice to distribute the disinfectant on the towelettes. If the towelettes are excessively wet or dripping, squeeze the excess (dripping) liquid out before using them on the meter.
- Do not get water or other liquids inside the meter or immerse the meter or lancing device in water or any other liquids.
- Do not use glass, household cleaners, or ammonia on the meter or lancing device. Use only Clorox HealthCare Bleach Germicidal Wipes.
- The cleaning step should be performed prior to the disinfection step.

4. To disinfect your meter or lancing device, wipe all external surface with a fresh Clorox Healthcare Bleach Germicidal Wipes. Allow the surface of meter or lancing device to remain wet for at least 1 minute at room temperature, wipe all external surface with a fresh Clorox Healthcare Bleach Germicidal Wipe.

NOTE:

- Avoid wetting the meter data port and test strip holder.



5. Discard used towel in a sealed container where it will not be touched by others.
6. Allow to air dry.
7. Wash hands with soap and water and dry thoroughly.

NOTE:

- If the meter or lancing device is being operated by a second person who is providing testing assistance to the user, the meter or lancing device should be cleaned and disinfected prior to use by the second person.
- Keep Clorox Healthcare Bleach Germicidal Wipes out of reach of children and stored according to its instruction.
- Do not flush towels down toilet.

IMPORTANT:

If you notice any of the below signs after cleaning and disinfecting your meter or lancing device; stop using the device and contact customer service immediately at www.ketocoachx.com or 1-800-587-5496.

- Control solution out of range.
- Clouding meter LCD display.
- Corrosion or erosion of plastic housing or buttons.
- Cracking of plastic housing.
- Malfunction of any meter button.

Purchase Information for Clorox Healthcare Bleach Germicidal Wipes

Clorox is the product of Clorox, the catalog number is 30577 (150 count) or 35309 (70 count).

Follow the website below to find your nearest Clorox Sales Representative.

<http://www.cloroxprofessional.com/products/clorox-germicidal-wipes/at-a-glance/#>

To find a local distributor in your area, call Customer Service at 800.234.7700, Mon-Fri 8:30am - 5:00pm EST.

You can also purchase on <http://www.amazon.com> or in the retail store Walmart or Target.

If you need assistance or have question about cleaning and disinfection for the meter, please contact customer service at www.ketocoachx.com or call 1-800-587-5496.

Storage and Precautions



- Handle the meter with care; severe shock, such as dropping the meter, could damage the electronics.
- The meter and the test strips are designed to be used within the temperature ranges between 10°C ~40°C (50°F ~104°F) and relative humidity less than 85% for ketone test.
- Avoid leaving the meter in extremely hot or cold places, such as near a heat source or in an extremely hot or cold car.
- Do not store or use the meter or test strips where they may be exposed to high humidity levels, such as in a bathroom or kitchen.
- Always close bottle cap immediately after removing a test strip and make sure it is closed tightly.
- Do not take the meter apart. Doing so will void the warranty.
- Do not use this meter in a dry environment, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharges in a dry environment.
- Do not use this meter near cellular or cordless telephones, walkie-talkies, garage



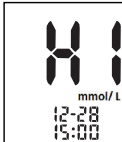
door openers, radio transmitters, or other electrical equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.


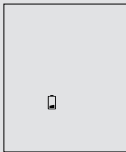
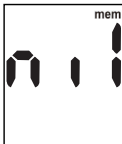
- Dispose of the meter according to your local regulations for correct disposal.
- Discard used lancet and test strip according to your local regulations.

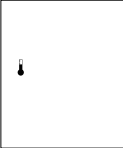
Solving Problems

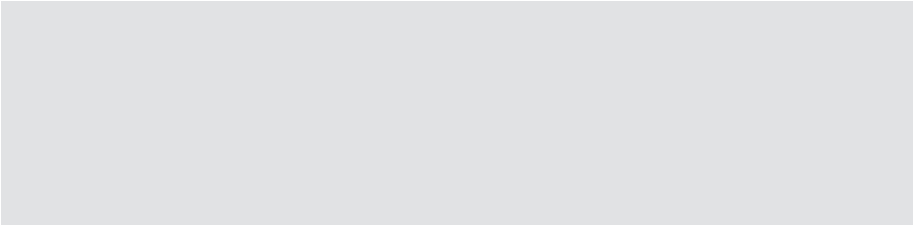
This section details the significant display screen messages and error codes you may encounter when using your KetoCoach™ Meter and KetoCoach™ Blood Ketone Test Strip.

Message	What It Means	What You Should Do
 <p>The image shows a digital display with the text 'Er 1' in a large, bold, black font. Below it, the date '12-15' and time '15:00' are displayed in a smaller font.</p>	Damaged meter electronic or test strip	<ul style="list-style-type: none"> • Replace the batteries and turn the meter on again. • Remove the test strip and insert a new test strip again. • If problem persists, contact us at www.ketocoachx.com.
 <p>The image shows a digital display with the text 'Er 2' in a large, bold, black font. Below it, the date '12-15' and time '15:00' are displayed in a smaller font.</p>	Used or contaminated test strip	<ul style="list-style-type: none"> • Remove the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop icon before you add blood or control solution sample.

Message	What It Means	What You Should Do
	Not enough sample on the test strip to start	<ul style="list-style-type: none">Remove the test strip and repeat the test with a new test strip. See Testing Your Blood Ketones on page 31.
	Test strip removed during countdown	<ul style="list-style-type: none">Turn off the meter and repeat the test with a new test strip.
	Ketone test result higher than 8.0 mmol/L	<ul style="list-style-type: none">Wash and dry your hands and repeat the test using a new test strip. If the result is still “HI”, contact your physician or healthcare professional immediately.

Message	What It Means	What You Should Do
	Ketone test result lower than 0.1 mmol/L	<ul style="list-style-type: none"> Below 0.6 mmol/L (including LO) is a normal blood ketone level. See Understanding Your Test Results on page 38.
	Low battery	<ul style="list-style-type: none"> Change the batteries according to instructions for Inserting (or Changing) the Battery on page 13.
	No memorized results in the meter	<ul style="list-style-type: none"> Check if the date and time on your meter is set up. See Setting Up Your New System on page 13. Start testing your blood ketone, see Testing Your Blood Ketone on page 31.

Message	What It Means	What You Should Do
	Temperature out of range	<ul style="list-style-type: none">• Move the meter into an area that is between 10°C ~40°C (50°F ~104°F) for ketone test, and allow 10 to 15 minutes for it to reach the new temperature.



Product Warranty

AmVentureX warrants the KetoCoach™ Meter to be free of defects in workmanship and materials under normal use for a period of five (5) years from the date of purchase to the consumer.

The liability of AmVentureX is limited to repair or replacement and in no event shall AmVentureX be liable for any collateral or consequential damages or loss.

Instruments subjected to misuse, abuse, neglect, unauthorized repair or modification will be excluded from this warranty.

This guarantee specifically excludes expendables and consumables.

All warranty claims must be directed to the AmVentureX authorized dealer responsible for the sale of the system.

The warranty applies only to the original purchaser of the system.

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Specifications

Test Strips:	KetoCoach™ Blood Ketone Test Strip
Test Range:	0.1~8.0 mmol/L
Calibration:	Plasma
Blood Sample Size:	≥ 0.8 µL
Hematocrit Range:	20~60%
Display Type:	LCD screen with back lighting
Memory:	500 test results with date and time
Dimensions:	96L x 58W x 16H (mm)
Weight:	49g (without batteries)
Battery:	2 x CR 2032 3V Lithium coin cell batteries
Battery Life:	1000 tests of continuous use or one year
Automatic Power-off:	After 1.5 minutes of inactivity
Operating Temperature:	10°C ~40°C (50°F ~104°F)
Relative Humidity:	20%~90%
Alarms:	3 for ketone test
Storage/Transport Condition:	Meter at -20°C~50°C (-4°F ~122°F), <93% RH Ketone test strip at 4°C~30°C (-4°F ~122°F), 10%~85% RH

Supplies

S11006	KetoCoach™ Kit
S11007	KetoCoach™ meter only
S5640790	KetoCoach™ Blood Ketone Test Strip, 10's foiled
S5640789	KetoCoach™ Blood Ketone Test Strip, 25's foiled
S5640791	KetoCoach™ Blood Ketone Test Strip, 50's foiled
S5800335	KetoCoach™ Ketone Control Solution L2