



TD-4279

# β-Ketone & Blood Glucose Monitoring System

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## Owner's Manual





## Dear TD-4279 keto-mojo System Owner:

Thank you for purchasing the **TD-4279**  $\beta$ -Ketone & Blood Glucose Monitoring System. This manual provides important information to help you to use the system properly. Before using this product, please read the following contents thoroughly and carefully.

The System measures both blood glucose and  $\beta$ -ketone. Regular monitoring of your blood glucose and  $\beta$ -ketone levels can help you and your doctor gain better control of your diabetes. Due to its compact size and easy operation, you can use the **TD-4279**  $\beta$ -Ketone & Blood Glucose Monitoring System to easily monitor your blood glucose and  $\beta$ -ketone levels by yourself anywhere, any time.

If you have other questions regarding this product, please contact KETO-CHECK at 800.513.1965 (10am - 4pm PST) or place of purchase.

### Intended Use

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

The test for haematocrit (HCT) as part of the system, is intended for use in the *in vitro* quantification of packed red blood cell volume fraction in capillary whole blood as an aid in monitoring the status of total volume of red blood cells. The test reading of haematocrit (HCT) is used only to determine whether the blood test sample is within the acceptable range of  $\beta$ -ketone & blood glucose monitoring system monitoring system. It should not be used for the diagnosis of anaemia or erythrocytosis.

# IMPORTANT SAFETY PRECAUTIONS

## READ BEFORE USE

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

For more information, please visit

1. “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>
2. “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>

1. Use this device ONLY for the intended use described in this manual.
2. Do NOT use accessories which are not specified by the manufacturer.
3. Do NOT use the device if it is not working properly or if it is damaged.
4. Do NOT use the equipment in places where aerosol sprays are being used, or where oxygen is being administered.
5. Do NOT under any circumstances use the device on neonates or infants.
6. This device does NOT serve as a cure for any symptoms or diseases. The data measured is for reference only.
7. Before using this device, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
8. Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.

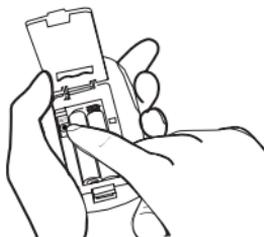
9. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as this may interfere with the accurate operation.
10. Proper maintenance and periodically control solution test are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact your local customer service or place of purchase for help.

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(a)



(b)



(c)



(d)



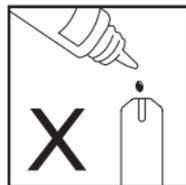
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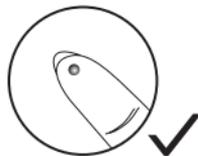
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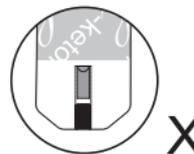
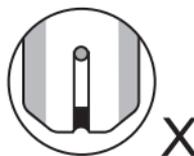
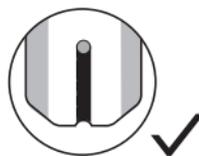
(g)



(h)



(i)



(j)



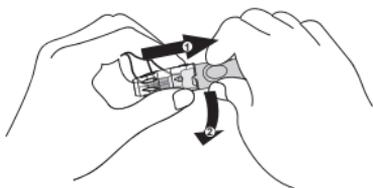
(k)



(l)



(m)



(n)



# **BEFORE YOU BEGIN**

## **Important Information**

- Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- If your blood glucose or  $\beta$ -ketone results are lower or higher than usual, and you do not have any symptoms of illness, first repeat the test. If you have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of your healthcare professional.
- Use only fresh whole blood samples to test your blood glucose or  $\beta$ -ketone. Using other substances will lead to incorrect results.
- If you are experiencing symptoms that are inconsistent with your blood glucose or  $\beta$ -ketone test results and you have followed all the instructions given in this owner's manual, contact your healthcare professional.
- The device should not be used on severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Please consult the healthcare professional before use.
- **Limitation**  
The device should not be used on individuals in hyperglycemic-hyperosmolar state, with or without ketosis; not for neonatal use; not for use on critically ill patients.

## Test Principle

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

## Contents of System

Your new keto-mojo  $\beta$ -ketone & blood glucose monitoring system kit includes:

1. Meter
2. Owner's Manual
3. Quick Start User Guide
4. 2 x 1.5 V AAA alkaline batteries

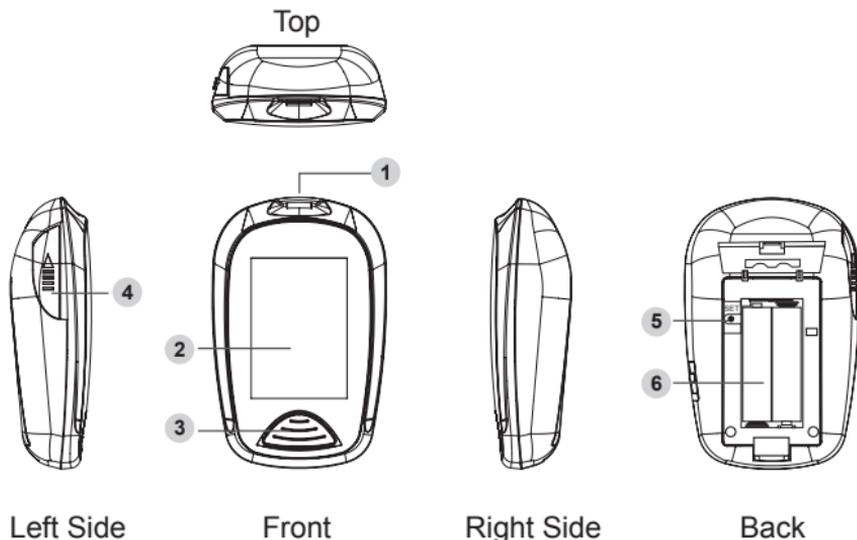
Test strips (c), control solutions (d), sterile lancets (f) or lancing device (e) are not included in the kit. They must be purchased separately. Please make sure you have those items needed for a test beforehand.

The strip port cable is not provided in the kit but an accessory for the data transmission feature connecting to your personal computer (see section Downloading Results onto your Computer). Please contact KETO-CHECK at 800.513.1965 (10am - 4pm PST) or place of purchase.

### **NOTE:**

If any items are missing from your kit or opened prior to use, please contact local customer services or place of purchase for assistance.

# Meter Overview



## 1 Test Strip Slot / Strip Communication Port

Insert test strip here to turn the meter on for testing.

Download test results with a strip port connection cable.

## 2 Display Screen

## 3 Main Button (M)

Enter the meter memory and silence a reminder alarm.

## 4 Test Strip Ejector

Eject the used strip by pushing up this button.

## 5 SET Button (S)

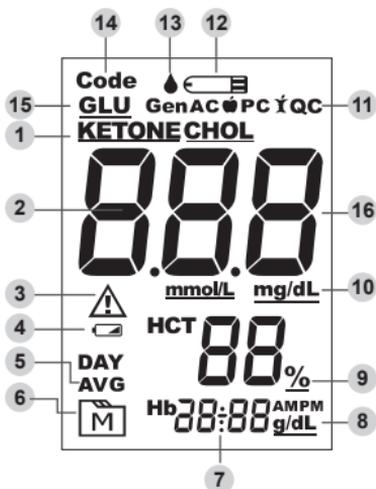
Enter and confirm the meter settings.

## 6 Battery Compartment

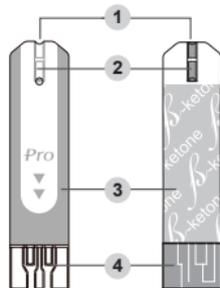
## Display Screen

- |                                  |                      |
|----------------------------------|----------------------|
| 1 Ketone Symbol / Ketone Warning | 12 Test Strip Symbol |
| 2 Glucose Level / Ketone Level   | 13 Blood Drop Symbol |
| 3 Error Warning                  | 14 Code              |
| 4 Low Battery Symbol             | 15 Glucose Symbol    |
| 5 Day Average                    | 16 Alarm Reminder    |

- |                                      |
|--------------------------------------|
| 6 Memory Symbol                      |
| 7 Hb Level / Time / Date             |
| 8 Hb Unit                            |
| 9 HCT Level                          |
| 10 Glucose / Ketone Measurement Unit |
| 11 Measurement Modes                 |
- Gen – any time of day  
AC – before meal  
PC – after meal



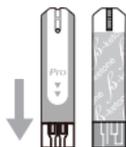
## Test Strip



(for glucose test)

(for ketone test)

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



### ATTENTION:

The front side of test strip should face up when inserting test strip.

Test results may be wrong if the contact bar is not fully inserted into the test slot.

### NOTE:

The TD-4279 keto-mojo  $\beta$ -Ketone & Blood Glucose Monitoring System should only be used with TD-4279 keto-mojo Glucose or  $\beta$ -Ketone Test Strips. Using other test strips with this monitoring system can produce inaccurate results.

# SETTING THE METER

Before using your meter for the first time, you should check and update these settings.

## **Entering the Setting Mode (a)**

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

### **1. Setting the date**

The sequence of the date setting is: YEAR → MONTH → DAY. With the YEAR / MONTH / DAY flashing in sequence, press **M** until the correct year/month/day appears. Press **S**.

### **2. Setting the time format**

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

### **3. Setting the time**

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

### **4. Setting the unit of measurement**

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

### **5. Setting the buzzer**

With the buzzer displays, press **M** to switch between “On” and “OFF”. Press **S**.

### **6. Deleting the memory**

With “dEL” and a “” on the display, press **M** and select “no” to keep the results in memory then press **S** to skip. To delete all the results, press **M** and select “yes” to delete all the memory records.

### **7. Setting the reminder alarm**

Your meter has four reminder alarms. The meter will display “OFF” and “AL1”. If you don’t want to set an alarm, press **S** to skip this step; Or press **M** to select “On”, then press **S**.

With the hour/minute flashing in sequence, press **M** to select the correct hour/minute. Press **S** and go to the next alarm setting.

**NOTICE:**

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

## **8. Setting the backlight**

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

**Congratulations! You have completed all settings!**

**NOTE:**

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

# **THE MEASURING MODES**

## **For Blood Glucose Testing**

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

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

## **For $\beta$ -Ketone Testing**

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

# QUALITY CONTROL TESTING

## When Should the Control Solution Test be Performed?

- if it is mandatory following the local regulations in your country,
- if you suspect the meter or test strips are not working properly,
- if your test results are not consistent with how you feel, or if you think the results are not accurate,
- to practice the testing process, or
- if you have dropped or think you may have damaged the meter.

Test strips **(c)**, control solutions **(d)**, lancing device **(e)** or sterile lancets **(f)** may not be included in the kit (please check the contents on your product box). They can be purchased separately. Please make sure you have those items needed for a test beforehand.

## Performing a Control Solution Test

To perform a control solution test, you will need: **(b)**, **(c)** and **(d)**.

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

Wait for the meter to display “” and “”.

### 2. Apply control solution (g)

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

#### NOTICE:

- Your device will tag this measurement as QC test automatically.
- To avoid contaminating the control solution, do not directly apply control solution onto a strip.

### 3. Read and compare the result

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

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

### Out-of-range results

If you continue to have test results fall outside the range printed on the test strip vial, the meter and strips may not be working properly. Do NOT test your blood. Call KETO-CHECK at 800.513.1965 (10am - 4pm PST) for help.

#### **NOTE:**

- There is no HCT and Hb display function while the meter is in QC mode.
- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose or ketone level.
- See the **MAINTENANCE** section for important information about your control solution.

# TESTING WITH BLOOD SAMPLE

## **WARNING:**

To reduce the chance of infection:

- Never share a lancet or the lancing device.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.
- Wash and dry your hands thoroughly after handling the meter, lancing device and test strips to prevent infection. For more information, please refer to the “Cleaning and Disinfection” section.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be decontaminated prior to use by the second person.

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

## **Preparing the Lancing Device for Blood Testing**

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

### **Preparing the Puncture Site**

Stimulating blood perfusion by rubbing the puncture site before blood extraction significantly reduces variations between measurements.

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

- Select the puncture site at fingertips (for glucose test).
- Select the puncture site either at fingertips or palm (please see section 'Alternative Site Testing' [AST]).
- Rub the puncture site for about 20 seconds before penetration.
- Clean the puncture site using cotton moistened with 70% alcohol and **let it air dry**.

- Use a clear cap (optional) while setting up the lancing device (for  $\beta$ -ketone test).
- **Fingertip testing (l)**  
Press the lancing device's tip firmly against the lower side of your fingertip. Press the release button to prick your finger; a click indicates that the puncture is complete.
- **Blood from site other than the fingertip (m) (for  $\beta$ -ketone test)**  
Replace the lancing device cap with the clear cap for AST. Pull the cocking control back until it clicks. When lancing the palm, avoid lancing the areas with obvious veins because of excessive bleeding.

#### NOTE:

- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- Please consult your health care professional before you begin AST (for  $\beta$ -ketone test).
- It is recommended that you discard the first drop of blood as it may contain tissue fluid, which may affect the test result.

## Performing a Blood Glucose or $\beta$ -Ketone Test

To perform a blood glucose or  $\beta$ -ketone test, you will need: **(b)**, **(c)**, **(e)** and **(f)**.

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

Wait for the meter to display “”, “”, and "GLU" or "KETONE"

### 2. Select the appropriate measuring mode by pressing **M**

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

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

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

Gently apply the drop of blood to the absorbent hole of the test strip at a tilted angle. Confirmation window should be completely filled if enough blood sample has been applied. Do **NOT** remove your finger until you hear a beep sound.

##### **NOTE:**

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

#### 5. Read your result

The result of your blood glucose test with HCT/ Hb levels or the result of your  $\beta$ -ketone test will appear after the meter counts down to 0. The blood glucose result with HCT/ Hb levels or the  $\beta$ -ketone result will be stored in your memory automatically.

#### 6. Eject the used test strip (j)

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

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

**WARNING:**

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

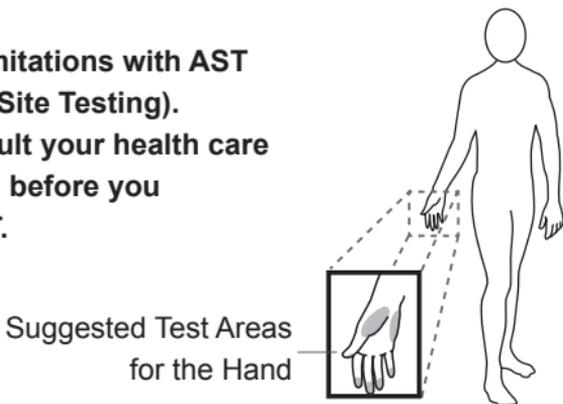
## Alternative Site Testing (for $\beta$ -Ketone Test)

In addition to using your fingertips, you can test on your palms.

**Important:**

**There are limitations with AST (Alternative Site Testing).**

**Please consult your health care professional before you perform AST.**



### **When to use AST?**

Food, medication, illness, stress and exercise can affect ketone levels. Capillary blood at the fingertip reflects these changes faster than capillary blood at other sites. Thus, when testing ketone during or immediately after a meal, physical exercise, or any other event, **take a blood sample from your finger only.**

We strongly recommend that you perform AST **ONLY** at the following times:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

Do **NOT** use AST if:

- You think your ketone is low.
- Your AST results do not match the way you feel.
- Your routine ketone results often fluctuate.

# METER MEMORY

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

## Reviewing Test Results

### 1. Press and release **M**.

“**M**” will appear on the display. Press **M** again, and the first reading you see is the last blood glucose result along with HCT/Hb value, date, time and the measuring mode or you will see the last  $\beta$ -ketone result along with date, time and the measuring mode.

**2. Press M** to recall the test results stored in the meter. **After the last glucose or  $\beta$ -ketone test result, press M again and the meter will switch off.**

## Reviewing Blood Glucose Day Average Results

**1. Press and release M.** When “**M**” appears on the display, keep pressing **M** for 3 seconds until the flashing “**DAY AVG**” appears. Release **M** and then your 7-day average result measured in general mode will appear on the display.

**2. Press M to review** 14-, 21-, 28-, 60- and 90- day average results stored in each measuring mode in the order of Gen, AC, and then PC.

**3. Exit the meter memory.** Keep pressing the **M** and the meter will switch off after displaying the last test result.

### NOTE:

- Any time you wish to exit the memory, keep pressing **M** for 5 seconds or leave it without any action for 3 minutes. The meter will switch off automatically.
- Control solution results are **NOT** included in the day average.

# **DOWNLOADING RESULTS ONTO A COMPUTER**

## **Data Transmission Via Cable**

You can use your meter with a strip port cable and the Healthcare Software System to view test results with HCT/Hb levels on your personal computer. To learn more about the Healthcare Software System or to obtain a strip port cable separately, please contact the local customer services or place of purchase for assistance.

### **1. Obtaining the required cable and installing the software**

To download Healthcare Software System, please visit TaiDoc's website: [www.taidoc.com](http://www.taidoc.com)

### **2. Connecting to a personal computer**

Connect the strip port cable to a USB port on your computer. With the meter switched off, connect the other end of the strip port cable to the strip communication port. "PC" will appear on the meter display, indicating that the meter is in communication mode.

### **3. Data transmission**

To transmit data, follow the instructions provided with the software. Results will be transmitted with the date and time. Remove the cable and the meter will automatically switch off.

#### **WARNING:**

While the meter is connecting to the PC, it will be unable to perform a blood glucose or  $\beta$ -ketone test.

# MAINTENANCE

## Battery

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

### Low Battery Signal

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

1. The “” **symbol appears along with display messages:** The meter is functional and the result remains accurate, but it is time to change the batteries.
2. The “” **symbol appears with E-b and ** : The power is not enough to do a test. Please change the batteries immediately.

### Replacing the Battery (k)

**To replace the batteries, make sure the meter is turned off.**

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

#### NOTE:

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

## Caring for Your Meter

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

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

Cleaning and disinfection are different. Cleaning is the process of removing dirt (e.g. food debris, grease, dust), while disinfection is the process of killing germs (e.g. bacteria and viruses).

### **When to clean and disinfect the meter**

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

### **How to clean and disinfect the meter**

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

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

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

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

## Disinfecting Procedures

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

Improper system cleaning and disinfection may result in meter malfunction. If you have a question, please contact local customer service at 800.513.1965 for assistance.

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

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

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

- Scratches or abrasions on meter are higher than acceptable
- Please contact the customer service for a replacement meter if any of the signs of deterioration are noticed.**

**NOTE:**

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

## Caring for Your Test Strips

- Storage conditions: 35.6°F to 86°F (2°C to 30°C) for both blood glucose test strips and blood  $\beta$ -Ketone test strips. Relative humidity of both is between 10% ~ 85%. Do **NOT** freeze.
- Store your blood glucose test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.
- After removing a glucose test strip from its vial, immediately close the vial cap tightly.
- Touch the glucose and ketone test strips with clean and dry hands.
- Use each test strip immediately after removing it from the vial.
- Write the opening date on the vial label when you first opened it. Discard remaining blood glucose or  $\beta$ -ketone test strips after 6 months.

- Do not use test strips beyond their expiry date. This may cause inaccurate results.
- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

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

## **Important Control Solution Information**

- Use only Our control solution with your meter.
- Do not use the control solution beyond the expiry date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature 68°F ~ 77°F (20°C ~ 25°C). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.
- Store the control solution tightly closed at temperatures between 35.6°F ~ 86°F (2°C ~ 30°C). Do **NOT** freeze.

# SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please contact your local customer service. Do not attempt to repair yourself and never try to disassemble the meter under any circumstances.

## Result Readings (for glucose test)

MESSAGE	WHAT IT MEANS
Lo	< 10 mg/dL (0.6 mmol/L)
<b>KETONE</b>	≥ 240 mg/dL (13.3 mmol/L)
Hi	> 700 mg/dL (38.9 mmol/L)

## Result Readings (for $\beta$ -ketone test)

MESSAGE	WHAT IT MEANS
Lo	< 0.1 mmol/L
06 <small>mmol/L</small>	0.1 to 8.0 mmol/L
Hi	> 8.0 mmol/L

## How to interpret blood Ketone results

Your Ketone reading	Interpretation
Below 0.6mmol/L	This is normal
Between 0.6 and 1.5 mmol/L	You may require medical assistance; contact your Diabetes healthcare team for advice.
Above 1.5mmol/L	Risk of Diabetic ketoacidosis; call your Diabetes healthcare team immediately.

## References

1. Schade DS, Eaton RP. Metabolic and clinical significance of ketosis. *Special Topics in Endocrinology and Metabolism* 1982;4:1-27.
2. Wiggam MI, O’Kane MJ, Harper R, Atkinson AB, Hadden DR, Trimble ER, Bell PM. Treatment of diabetic ketoacidosis using normalization of blood 3-hydroxybutyrate concentration as the endpoint of emergency management. *Diabetes Care* 1997;20:1347-52.
3. 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;26:343-8.
4. Ubukata E. Diurnal variation of blood  $\beta$ -Ketone bodies in insulin-dependent diabetes mellitus and noninsulindependent diabetes mellitus patients: The relationship to serum C-peptide immunoreactivity and free insulin. *Ann Nutr Metab* 1990;34:333-42.
5. 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;37:1470-77.
6. Hale PJ, Crase J, Natrass M. Metabolic effects of bicarbonate in the treatment of diabetic ketoacidosis. *Br Med J* 1984;289;1035-8.

## Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
E-b	Appears when the batteries are too low.	Replace the batteries immediately.
E-2	Expired code chip.	Repeat the test with a new lot of test strip.
E-U	Appears when a used test strip is inserted.	Repeat with a new test strip.
E-t	Appears when ambient temperature is above or below system operation range.	System operation range is 10°C to 40°C (50°F to 104°F). Repeat the test after the meter and test strip are in the above temperature range.
E-0, E-A, E-E, E-C	Problem with the meter.	Repeat the test with a new test strip. If the meter still does not work, please contact the local customer service for assistance.
E-F	Appears when test strip is removed while counting down, and insufficient blood volume. Or the HCT result is above 75 %.	Review the instructions and repeat test with a new strip. If the problem persists, please contact the local customer service for help.

# Troubleshooting

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

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Replace the batteries.
Test strip inserted upside down or incompletely.	Insert the test strip with contact bars end first and facing up.
Defective meter or test strips.	Please contact customer services.

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

POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off (3 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing “  <p>3. If the control solution testing result is out of range:</p>

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

# DETAILED INFORMATION

## Reference Values

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

Time of day	Normal blood glucose range for people <b>without</b> diabetes (mg/dL)
Fasting and before meal	< 100 mg/dL (5.6 mmol/L)
2 hours after meals	< 140 mg/dL (7.8 mmol/L)

American Diabetes Association. Standards of medical care in diabetes- 2016; 39 (supp.1 Diabetes Care): S16.

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

$\beta$  -OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill. If your  $\beta$ -Ketone result is 0.0 mmol/L, repeat the  $\beta$ -Ketone test with new test strips. If the same message appears again or the result does not reflect how you feel, contact your healthcare professional.

Follow your healthcare professional's advice before you make any changes to your diabetes medication programme. If your  $\beta$ -Ketone result is between 0.6 and 1.5 mmol/L, this may indicate development of a problem that could require medical assistance. Follow your healthcare professional's instructions. If your  $\beta$ -Ketone result is higher than 1.5 mmol/L, contact your healthcare professional promptly for advice and assistance. You may be at risk of developing diabetic ketoacidosis (DKA).

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

## Comparing Meter and Laboratory Results

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

### Before going to the lab:

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

### While staying at the lab:

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

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

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

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

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

## SYMBOL INFORMATION

SYMBOL	REFERENT
	<i>In vitro</i> diagnostic medical device
	Consult instructions for use
	Temperature limitation
	Do not use if package is damaged

# SPECIFICATIONS

**Model No.:** TD-4279

**Dimension & Weight:** 96 (L) x 61 (W) x 26 (H) mm, 67.2 g

**Power Source:** Two 1.5V AAA alkaline batteries

**Display:** LCD

**Memory:** 1000 measurement results with respective date and time

**External Output:** Strip port cable

Auto electrode insertion detection

Auto sample loading detection

Auto reaction time count-down

Auto switch-off after 3 minutes without action

Temperature Warning

**Operating Condition:**

50°F ~ 104°F (10°C ~ 40°C), 10% to 85% R.H. (non-condensing)

**Meter Storage / Transportation Conditions:**

-4°F ~ 140°F (-20°C ~ 60°C), below 95% R.H.

**Glucose Test Strip Storage / Transportation Conditions:**

35.6°F to 86.0°F (2°C to 30°C), 10% to 85% R.H. (non-condensing),  
up to 21 months for un-opened vial

**β-Ketone Test Strip Storage / Transportation Conditions:**

35.6°F to 86.0°F (2°C to 30°C), 10% to 85% R.H. (non-condensing),  
up to 18 months for un-opened vial

**Measurement Units:**

Glucose: Either mg/dL or mmol/ (Default mg/dL)

β-ketone: mmol/L

**Measurement Range:**

Glucose : 10 ~ 700 mg/dL (0.56 ~ 38.89 mmol/L)

β-ketone: 0.1 ~ 8.0 mmol/L

**life:** 5 years

This device has been tested to meet the electrical and safety requirements of:  
IEC/EN 61010-1, IEC/EN 61010-2-101, IEC/EN 61326-1, IEC/EN 61326-2-6.





Distributed by

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Please contact your healthcare provider outside hours of operation.

For self-testing

