Medisign *MediKeto 82 BT*

blood β-ketone monitoring system

User Manual

Introduction

Thank you for choosing the Medisign ***MediKeto 82 BT*** blood β-ketone monitoring system to help monitor your blood β-ketone levels. The Medisign ***MediKeto 82 BT*** blood β-ketone monitoring system is designed to be accurate and easy to use. This user manual contains all the information needed to use and maintain the Medisign ***MediKeto 82 BT*** blood β-ketone monitoring system. Please read this User Manual carefully before you start the test and do a quality control test. If you have question about the control test, please consult with your healthcare professional. Please confirm the measuring unit on the display is correct with every test result.

If you need assistance, please contact Customer Service. If you have questions or need assistance outside the days and hours of operation, please contact your health care professional.

IMPORTANT SAFETY INFORMATION

- Meters that come into contact with blood present a potential risk of transmitting infectious diseases. To prevent infections and/or cross-contamination, maintain good hand hygiene and clean your Medisign ***MediKeto 82 BT*** blood β-ketone meter as well as the corresponding accessories regularly.
- Healthcare Professionals performing blood β-ketone tests with this system on multiple patients must always wear gloves and should follow the infection control policies and procedures approved by their facility.
- The meter and lancing device are for single patient use only. Do **NOT** share them with anyone including family members.
- **NEVER** use lancets that has been used by someone else.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning.
- Do **NOT** leave the lancets in the lancing device after use, be sure to dispose of it according to instructions from your healthcare professional. Do **NOT** re-use a lancet.
- If you have taken the cap off of the lancet and the lancet has fallen to the ground, do **NOT** use it. Make sure you dispose of it and replace it with a new lancet.

⚠**CAUTION**

Keep the test strip, meter, lancing device, lancets and control solution away from all children and pets. Batteries and test strips may be a choking hazard.

Sign of Trouble

If you encounter any issues including the ones mentioned below, see the trouble shooting. If problems persist, do **NOT** use and contact Customer Service.

- The meter does **NOT** power on when the new test strip is inserted into the meter.
- The meter does **NOT** power on when you replace the batteries.
- The meter does **NOT** show the test result after the test is completed.
- The LCD does **NOT** display correctly or is distorted after changing the batteries.

Intended Use

The Medisign ***MediKeto 82 BT*** blood β-ketone monitoring system is intended to be used for the quantitative measurement of β-ketone (beta-hydroxybutyrate) in fresh capillary whole blood samples from the fingertips. Venous whole blood testing is limited to healthcare professionals use only. It is intended for self-testing outside of the body (in vitro diagnostic use only) by people with diabetes at home and healthcare professionals in a clinical setting as an aid to monitor the diabetes control. This system is **NOT** for use in diagnosis of or screening for diabetes, or for neonatal use.

Test Principle

β-Ketone in the blood sample reacts with beta-hydroxybutyrate dehydrogenase on the test strip respectively. This reaction produces a harmless current and the Medisign ***MediKeto 82 BT*** blood β-ketone meter measures the current, calculates the β-ketone level and displays the result. The strength of the current is dependent on the amount of β-ketone in the blood sample.

Important Information for the System

- Before using the Medisign ***MediKeto 82 BT*** blood β-ketone monitoring system, please read this manual carefully.
- Use this system only for blood β-ketone test.
- The Medisign ***MediKeto 82 BT*** blood β-ketone meter should be used with the Medisign ***MediKeto 82*** blood β-ketone test strips.
- If your test result does **NOT** match how you feel, call your physician or healthcare professional.
- **NEVER** ignore symptoms of high blood β-ketone.
- If you see "HI" displayed, your blood β-ketone level may be above 8.0 mmol/L, repeat the blood β-ketone test using a new test strip. If the meter persists same results, contact your physician or healthcare professional.
- This system could support your healthcare program but **NEVER** make major changes in your diabetes treatment program without consulting your physician.
- The results of this system should **NOT** be used for diabetic treatment or medications without consulting your doctor.
- Be sure to check the blood β-ketone measurement unit on the meter before the test. Use of the wrong blood β-ketone measurement unit may cause you to misinterpret the test results and result in incorrect treatment. Consult your healthcare professional if you have any questions about your blood β-ketone measurement units.
- Before the test you must make sure that the code number displayed on the meter matches the code number on the test strip vial or foil packet.
- If alcohol wipes are used to disinfect the fingertip, make sure the fingertip is completely dry before obtaining the blood sample.
- Before sampling blood, gently massage the hand and finger toward the puncture site to form a drop of blood. Do **NOT** squeeze excessively around the puncture site when you produce a drop of blood.
- Do **NOT** hold or shake the meter while it is testing.

Important Information for the Test Strip

- **NEVER** reuse a test strip that is either applied with blood or control solution. The test strips are for single use only.
- Before using, please check the test strip expiration date on the vial or the foil packet.
- Do **NOT** use test strips that have expired as it may cause inaccurate test results.
- Do **NOT** touch sampling end of the test strip.
- Do **NOT** smear the blood with sampling end of the test strip.
- Do **NOT** drop the blood directly on the sampling end of the test strip.
- Do **NOT** insert the test strip with force into the meter.
- Do **NOT** use wet, bent, scratched or visibly damaged test strips.
- You should use your test strip immediately after retrieving it from its vial or foil packet.
- Always keep the test strip vial closed immediately after retrieving the test strip.
- Do **NOT** use the test strip if the foil packet has a puncture or tear in it.
- For accurate results, fresh capillary whole blood and venous whole blood should be used. Arterial blood, plasma and serum are **NOT** suitable blood sample for the test.

Important Information for the Control Solution

- Use only the Medisign Ketone Control Solution. Other brands of control solutions will produce inaccurate results.
- Shake the Medisign Ketone Control Solution well before using.
- Always check the expiration date of the control solution. Do **NOT** use expired control solution.
- Do **NOT** apply control solution to the test strip directly from the vial.
- Do **NOT** add or apply a second drop of blood or control solution. This may cause a false result.
- Replace the cap of the control solution immediately after use.
- If the control test result falls outside of the range provided, it indicates that the system may **NOT** be functioning properly. Do **NOT** use the meter and please contact Customer Service.
- Control solution is **NOT** for human consumption or injection. Keep away from eyes.
- The range printed on the test strip vial or box is for the control solution only. It has nothing to do with your blood β-ketone levels.
- The results obtained from control testing do **NOT** reflect your personal blood β-ketone levels in any way.

Limitation

- This system is only for in vitro diagnostics use and for self-testing.
- This system is **NOT** designed for use with arterial, serum or plasma samples. Do **NOT** put urine on the blood β-ketone test strip.
- This system is **NOT** designed for use with neonatal.
- This system is **NOT** for screening or diagnosis of diabetes mellitus.
- Blood β-ketone testing must **NOT** use the forearm or palm site. Only use the fingertip for blood β-ketone testing.
- Hematocrit is the percentage of red blood cells in the blood. Testing outside of the Hematocrit level range of 20~60% may cause inaccurate result. If you do **NOT** know your hematocrit level, consult with your healthcare professional.
- Inaccurate results may occur if used at altitudes above 3,500m.
- This system is **NOT** for use on patients who are in shock or dehydrated.
- Inaccurate results may occur in severely hypotensive individuals.
- This system is **NOT** for use on critically ill patients.

Storage and Handling of the System

- Keep this system dry and keep away from the heat and direct sunlight.
- Avoid leaving the meter or test strips 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 at high humidity levels, such as in the bathroom or kitchen.
- Store the test strips in the original vial between 4 ~ 30℃, at indoor area. Do **NOT** freeze.
- The test strip may be stored in a refrigerator between 4 ~ 8℃. But it must be brought to room temperature before using.
- When properly stored, unopened test strips are stable until the expiration date printed on the vial or the foil packet.
- The test strips in the vial are good three (3) months after first opening date or until the expiration date, whichever comes first.
- Record the discard date on the test strip vial and discard any unused test strip after that date.
- The meter and the test strips are designed to be used within a temperature range of 10 ~ 40℃. Please keep the system operating temperature at a range between 10 ~ 40℃ for more than twenty (20) minutes before testing.
- Do **NOT** test if there is condensation (water build-up) on your meter and the test strip vial or the foil packet. Move your meter or a test strip vial or a foil packet to a cool, dry spot. Wait for the meter and a test strip vial or a foil packet surface to dry before testing.
- The meter, test strips, and control solution should be handled at the same temperature.
- Do **NOT** handle the test strips with wet or dirty hands.
- For accurate results, make sure your hands are clean and dry before retrieving test strip from its foil packet.
- Do **NOT** allow dirt or dust in the test strip slot in order to avoid affecting the system's performance.
- Dispose of used test strips, lancets according to instructions from your healthcare professional.
- Dispose of used batteries according to local regulations.
- Do **NOT** destroy, repair or transform the system at any time. If the equipment is used in a manner **NOT** specified by the manufacturer, the protection provided may be impaired.
- Handle the meter with care – severe shock, such as dropping the meter, could damage the electronics.
- The Applicable Pollution Degree of the intended environment for this system is Pollution Degree 2.

Storage and Handling of the Control Solution

- The control solution should be stored at indoor area between 4 ~ 30℃. Do **NOT** freeze.
- The control solution may be stored in a refrigerator between 4 ~ 8℃. But it must be brought to room temperature before using.
- The control solution is good three (3) months after first opening date or until the expiration date, whichever comes first.
- Record the discard date on the control solution vial and discard remained control solution after that date.
- The control solution test is recommended to be done at room temperature (20 ~ 25℃).

Important Information for Caring the Meter

- Clean your Medisign ***MediKeto 82 BT*** blood β-ketone meter once per week at a minimum.
- Do **NOT** get water inside the meter. **NEVER** immerse the meter or hold it under running water or spray any cleaning solution directly onto the meter.
- Do **NOT** try to get moisture on the test strip, test strip slot or serial port.
- Do **NOT** use glass cleaners or household cleaners or corrosive liquid (e.g. Benzene, Acetone) on the meter.
- Please use a soft cotton cloth to wipe the system.
- Squeeze the excess liquid from the cloth before you wipe the meter.
- The meter must be turned off when you clean the meter.

Table of Contents

1. About the Medisign *MediKeto 82 BT* blood β-ketone monitoring system 8

- Contents of Kit 8
- Medisign *MediKeto 82 BT* Blood β-Ketone Meter 8
- Meter Display Screen 9
- Medisign *MediKeto 82* Blood β-Ketone Test Strip 10
- Medisign Ketone Control Solution 10
- Medisign Ketone Check Strip 10

2. Settings11

- Inserting (or Replacing) the Batteries 11
- Set Date and Time 11
- Acoustic Signal 11
- Delete Test Results 12
- Exit Settings 12

3. Control Solution Testing 13

- Performing a Control Solution Test 14
- Performing the Check Strip Test 15

4. Testing Your Blood β-Ketone 16

- Preparing the Test 16
- Inserting the Medisign *MediKeto 82* Blood β-Ketone Test Strip 16
- Obtaining a Blood Drop 17
- Applying Blood 17
- Measuring Process 18
- Disposing Used Test Strips and Lancets 18

5. Understanding Your Blood β-Ketone Test Results 19

- Blood β-Ketone Results Interpretation 19

6. Displaying Stored Test Results 20

- Display of Test Results 20

7. Downloading Your Test Results to a PC 21

8. Pairing Your Meter 21

- Before Pairing Your Meter 21
- How to Pair Your Meter 21
- About Bluetooth 21

9. Cleaning Your Meter 22
10. Screen Messages and Troubleshooting 23
- Screen Messages 23
- Troubleshooting 24
11. System Specifications 24
12. Symbols 25
13. Disposing of the Meter 25
14. Additional Supplies 25
15. Product Warranty 25

1. About the Medisign *MediKeto 82 BT* blood β-ketone monitoring system

Contents of Kit

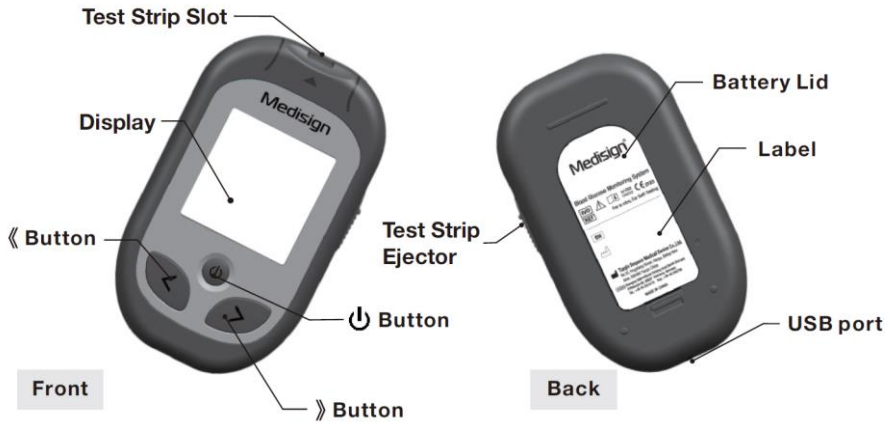
The Medisign ***MediKeto 82 BT*** blood β-ketone monitoring system includes the following items:

- Medisign ***MediKeto 82 BT*** blood β-ketone meter
- Medisign ***MediKeto 82*** blood β-ketone test strips (10 Tests)
- Lancing Device
- Lancets
- Battery (CR2032)
- Carrying Bag
- User Manual

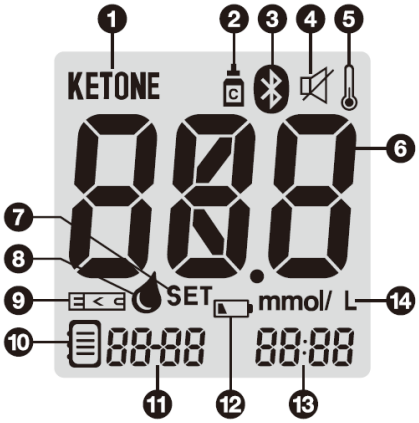
NOTE:

- The *Medisign* ***MediKeto 82*** *blood β-ketone test strips (for 25 Tests or 50 Tests), the Check Strip, and the Medisign Ketone Control Solution are required but* ***NOT*** *included and must be purchased separately. For additional information of other accessories, please contact your supplier, pharmacist, healthcare professional or Customer Service.*
- *The Test Strip may be provided with a foil packet for each or a vial for 10, 25 or 50 test strips.*

Medisign *MediKeto 82 BT* Blood β-Ketone Meter



Meter Display Screen

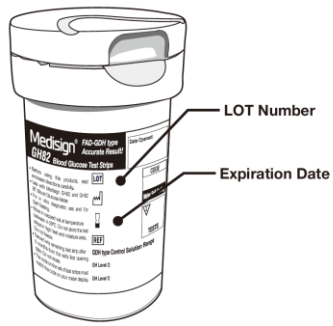


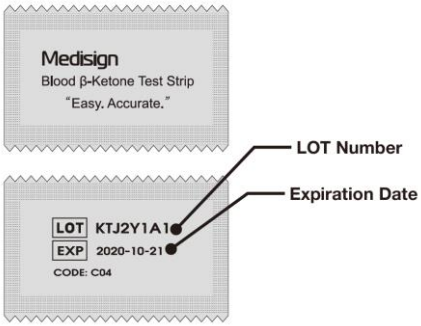
1	KETONE	Appears when the test strip is inserted
2		Symbol to mark the control solution test results
3		Appears when the meter pairs with a mobile device
4		Appears when the sound is set to OFF
5		Appears if the meter is out of operating temperature range
6	8.8.8	Segments to display test results or error messages
7	SET	Segments to display the Set-up mode
8		Appears when the meter is ready for application of blood or control solution.
9		Appears when test strip is inserted. Blinks when test strip is removed during the meter is on.
10		Appears when test results stored in memory are displayed
11	88-88	Segments to display date
12		Appears when the meter detects low battery power
13	88:88	Segments to display hour and minute of tests
14	mmol/ L	Segments to display the unit of measurement

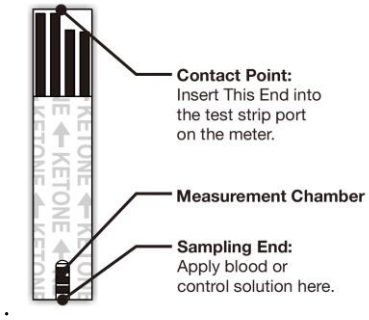
IMPORTANT

Be sure to check the blood β-ketone measurement unit on the meter before the test. Use of the wrong blood β-ketone measurement unit may cause you to misinterpret the test results and result in incorrect treatment. Consult your healthcare professional if you have any questions about your blood β-ketone measurement units.

Medisign *MediKeto 82* Blood β-Ketone Test Strip







Medisign *MediKeto 82* Blood β-Ketone Test Strip Vial	Medisign *MediKeto 82* Blood β-Ketone Test Strip Foil Packet	Medisign *MediKeto 82* Blood β-Ketone Test Strip

- The expiration date of the Medisign ***MediKeto 82*** blood β-ketone test strip can be found on the vial or the foil packet.

IMPORTANT

- The Medisign ***MediKeto 82 BT*** blood β-ketone meter should be used with the Medisign ***MediKeto 82*** blood β-ketone test strips.
- Before using, please check the test strip expiration date on the vial or the foil packet.
- The test strips in the vial are good three (3) months after first opening date or until the expiration date, whichever comes first.
- Record the discard date on the test strip vial and discard any unused test strip after that date.
- You should use your test strip immediately after retrieving it from its vial or foil packet.
- Always keep the test strip vial closed immediately after retrieving the test strip.
- Store the test strips in the original vial between 4 ~ 30℃, at indoor area.
- Keep the test strip away from the heat and direct sunlight. Do **NOT** freeze.
- The test strip may be stored in a refrigerator between 4 ~ 8℃. But it must be brought to room temperature before using.
- Do **NOT** test if there is condensation (water build-up) on your meter and the test strip vial or the foil packet. Move your meter or a test strip vial or a foil packet to a cool, dry spot. Wait for the meter and a test strip vial or a foil packet surface to dry before testing.
- Do **NOT** handle the test strips with wet or dirty hands.

Medisign Ketone Control Solution

The Medisign Ketone Control Solution is the standard blood β-ketone concentration solution required to perform a control test (See Control Solution Testing).
The Medisign Ketone Control Solution helps to validate the performance of the system. Run the control test to make sure the meter and test strips are working properly together, to practice testing procedure and when using a new package of the Medisign ***MediKeto 82*** blood β-ketone test strips.

Medisign Ketone Check Strip

The Medisign Ketone Check Strip verifies whether the Medisign ***MediKeto 82*** blood β-ketone meter is working properly.

2. Settings

Inserting (or Replacing) the Batteries

The batteries need to be inserted before using your Medisign ***MediKeto 82 BT*** blood β-ketone meter for the first time or when the batteries are low. When the batteries are low the screen will display and blink the ▭ on the bottom of the screen. It will be continuously shown until the meter becomes unusable due to low battery.

1. Open the battery compartment cover on the back of the meter.
2. Insert new batteries, with the (+) side facing up.
3. Replace the compartment cover back onto the meter.

⚠**CAUTION**

- Risk of explosion if battery is replaced by an incorrect type.
- Small items such as the battery cover and batteries are choking hazards.

IMPORTANT

- Dispose of used batteries according to local regulations.
- If the meter is **NOT** to be used for a long time, remove the battery to eliminate the risk of battery leakage.

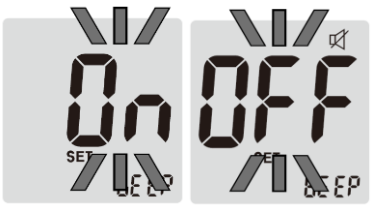
NOTE:

- *The meter can also be used with a single battery. If you install two (2) batteries, you can use it for a longer period.*
- *Whenever replacing the batteries, you need to reset the current date and time. However, test results stored will **NOT** be deleted.*

Set Date and Time

Press the ⏻ button to set the month, date, hours, minutes and year on after another. With the < or > button you can change the flashing value.

Acoustic Signal



Acoustic signals (bEEP) are activated by default. If you want to deactivate the acoustic signals, press the < or >

button to change the status from ON (activated) to OFF (deactivated). Confirm your choice with the ⏻ button.

NOTE: *Turning the beep sound on or off do* ***NOT*** *affect your blood β-ketone measurements.*

Delete Test Results

You have the option to delete the entire test results from meter memory. You will see dEL flashing on the screen. Press the < or > button to choose between YES (delete all test results) or NO (keep all test results).
Confirm your choice with the ⏻ button.

Exit Settings

Press ⏻ button for three (3) seconds to exit settings. No matter which steps the meter is set to, it will store the most recent setting and switches off.

NOTE: *You can start testing by inserting a test strip at any step.*

3. Control Solution Testing

The purpose of the control solution testing is to validate that the Medisign ***MediKeto 82 BT*** blood β-ketone meter is working properly with the test strips. The control solution may **NOT** be included in the kit. Please contact your pharmacist or healthcare professional or Customer Service to purchase the Medisign Ketone Control Solution.

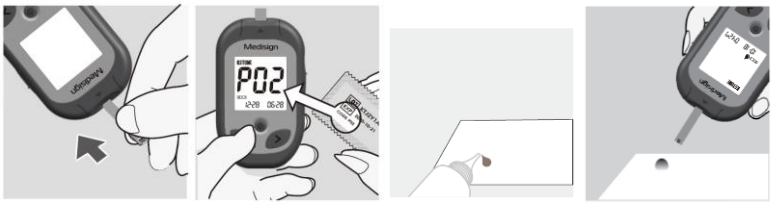
You should perform a control solution test when:

- Using the meter for the first time.
- You open a new packing box of test strips.
- You want to check the meter and test strips.
- At least once per week to verify that the meter and test strips are working properly together.
- Your test strips were stored in extreme temperature or humidity where is out of the specified storage conditions.
- The meter was dropped or damaged or gotten wet.
- You suspect the meter and test strips are **NOT** working properly together.
- Your test results do **NOT** agree with how you feel.
- You want to practice your test technique.
- Your test results appear to be abnormally high or low.

IMPORTANT

- Use only the Medisign Ketone Control Solution. Other brands of control solutions will produce inaccurate results.
- Always check the expiration date of the control solution. Do **NOT** use expired control solution.
- The control solution is good three (3) months after first opening date or until the expiration date, whichever comes first.
- Record the discard date on the control solution vial and discard remained control solution after that date.
- The control solution should be stored at indoor area between 4 ~ 30℃. Do **NOT** freeze.
- The control solution may be stored in a refrigerator between 4 ~ 8℃. But it must be brought to room temperature before using.
- Do **NOT** add or apply a second drop of control solution. This may cause a false result.
- Control solution is **NOT** for human consumption or injection. Keep away from eyes.
- Make sure the control solution vial is closed when **NOT** in use.
- If the control test result falls outside of the range provided, it indicates that the system may **NOT** be functioning properly. Do **NOT** use the meter and please contact Customer Service.
- The control solution test is recommended to be done at room temperature (20 ~ 25℃).

Performing a Control Solution Test



1. Insert the test strip with black lines facing upwards and pointing towards the test strip port. Make sure to firmly and completely insert the test strip into the meter. The meter will turn on automatically and the code number will appear on the screen. Verify that the code number displayed matches with the code number on the vial or the foil packet of the Medisign ***MediKeto 82*** blood β-ketone test strips. The code number on the picture above is for the example only. The code can be different for each test strip batch. If the two code numbers do **NOT** match, contact Customer Service.
2. When the blood drop symbol appears on the screen, shake the control solution vial well. Remove the cap. Squeeze the vial, discard the first drop and wipe off the dispenser tip with a clean tissue to ensure an accurate result. If large bubbles appear at the tip of the vial, wipe the bubbles off before applying a drop of control solution to the test strip. Then squeeze the vial again to receive a drop. Apply this drop of control solution to a clean and non-absorbent base. Close the lid of the control solution vial immediately after use.
3. Bring the test strip gently to the drop of control solution so the sampling end of the test strip touches the control solution. The drop of control solution will be drawn in automatically by the test strip.

IMPORTANT

- Replace the cap of the control solution immediately after use.
- Do **NOT** apply control solution to the test strip directly from the vial.

4. When the test strip measurement chamber is full, the meter will beep. The meter will count down from eight (8) seconds and then show the control test result. Make sure the test result on the screen is between the ranges printed on your Medisign ***MediKeto 82*** blood β-ketone test strip box or vial.
5. You can flag the control solution symbol by pressing the < or > button with the test result on the display and the test strip still in the meter.
6. Eject the test strip into a proper waste container.

NOTE: *Mark all control solution tests with the control solution symbol to distinguish them from blood β-ketone test results in the meter memory.*

IMPORTANT

- The range printed on the test strip vial or box is for the control solution only. It has nothing to do with your blood β-ketone levels.
- The results obtained from control testing do **NOT** reflect your personal blood β-ketone levels in any way.
- If the control solution test result falls outside of the range provided, do the following:
  - Do **NOT** test your blood β-ketone.
  - Make sure you are using the Medisign Ketone Control Solution.
  - Make sure the testing environment is between 10 ~ 40℃.
  - Make sure the Medisign Ketone Control Solution and test strips have **NOT** expired.
  - Repeat the test with a new test strip.
  - If the problem persists, contact Customer Service. If you have questions or need assistance outside the operational days and times, please contact your health care professional.

Performing the Check Strip Test

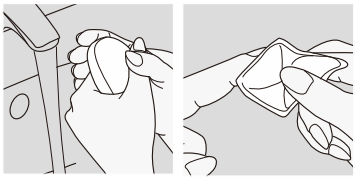
The Medisign Ketone Check Strip verifies whether the meter is working properly. Insert the check strip into the meter. The meter switches on automatically.
If the “OK” Message is **NOT** displayed on the screen after inserting the Medisign Ketone Check Strip, please contact Customer Service.

4. Testing Your Blood β-Ketone

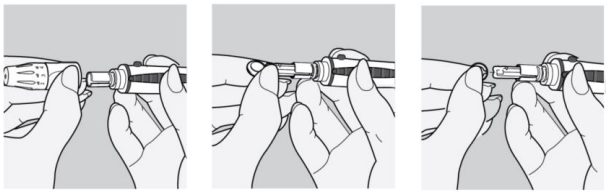
IMPORTANT SAFETY INFORMATION

- Meters that come into contact with blood present a potential risk of transmitting infectious diseases. To prevent infections and/or cross-contamination, maintain good hand hygiene and clean your Medisign ***MediKeto 82 BT*** blood β-ketone meter as well as the corresponding accessories regularly.
- Healthcare Professionals performing blood β-ketone tests with this system on multiple patients must always wear gloves and should follow the infection control policies and procedures approved by their facility.
- The meter and lancing device are for single patient use only. Do **NOT** share them with anyone including family members.
- **NEVER** use lancets that has been used by someone else.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning.

Preparing the Test



1. The easiest way to collect a drop of blood is to wash your hands with warm water and soap first. This promotes the blood circulation in the fingertips. Then dry your hands properly. The puncture site can alternatively be wiped with an alcohol- soaked swab. Please ensure that the site is completely dry before collecting the blood sample.



2. Prepare the lancing device and Turn the cap counterclockwise to remove it.
3. Insert the lancet into the lancet holder and push down firmly until it is fully seated. Do **NOT** twist the lancet.
4. Twist the protective disk until it separates from the lancet. Replace the lancing device cap. Turn it clockwise until it is snug fit.

NOTE: *If you have your lancing device already, please read information in your lancing device instruction for use.*

Inserting the Medisign *MediKeto 82* Blood β-Ketone Test Strip

1. Insert a test strip to turn on the meter automatically. Make sure it is inserted completely without bending the test strip. KETONE will appear on screen if the Medisign ***MediKeto 82*** blood β-ketone test

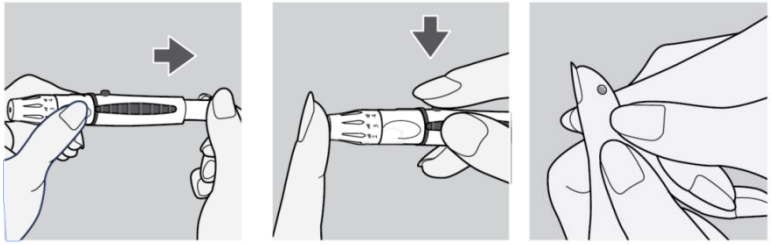
strip is inserted.

2. The meter identifies the code number automatically. Compare the code number displayed on the LCD with the code number shown on the vial or the foil packet. If they do **NOT** match, try again with another test strip. If the problem persists, please contact Customer Service.
3. When the blood symbol appears, it indicates that the meter is ready for blood β-ketone testing.

IMPORTANT

- Before the test you must make sure that the code number displayed on the meter matches the code number on the test strip vial or foil packet.

Obtaining a Blood Drop



1. Adjust the puncture depth setting if necessary, by turning the lancing device cap, number 1 is the shallowest depth while number 5 is the deepest. Slide the ejection/cocking control barrel back until it clicks. If it does **NOT** click, the lancing device may have been cocked when the lancet was inserted.
2. Hold the lancing device firmly against the side of your fingertip and lance the finger by pressing the release button of the lancing device.
3. Gently massage your finger towards the puncture site to produce a drop of blood.

NOTE: *Prick the side of fingertip to avoid soreness. To avoid calluses, choose a different testing site each time.*

IMPORTANT SAFETY INFORMATION

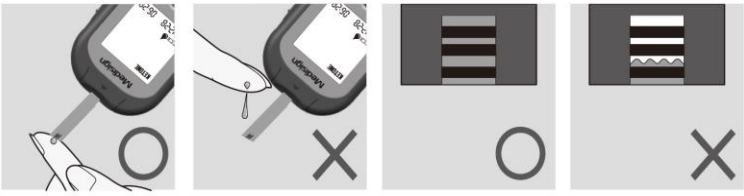
If you have taken the cap off of the lancet and the lancet has fallen to the ground, do **NOT** use it. Make sure you dispose of it and replace it with a new lancet.

IMPORTANT

- Do **NOT** squeeze excessively around the puncture site when you produce a drop of blood.
- If alcohol wipes are used to disinfect the fingertip, make sure the fingertip is completely dry before obtaining the blood sample.
- Blood β-ketone testing must **NOT** use the forearm or palm site. Only use the fingertip for blood β-ketone testing.

Applying Blood

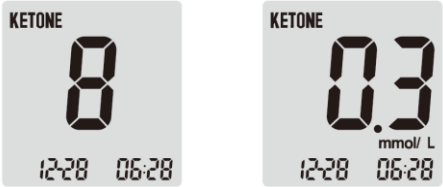
Place your finger on the tip of the test strip. Ensure that the blood is **NOT** applied from above.
The measurement chamber of the test strip draws the blood of your finger automatically. Your finger should remain still until the measuring chamber is completely filled and you hear the “beep” sound.



IMPORTANT

- The sample channel at the end of the test strip should show full. When you hear the beep sound, you have enough blood in the test strip.
- Do **NOT** put urine on the blood β-ketone test strip.
- Do **NOT** touch sampling end of the test strip.
- Do **NOT** smear the blood with sampling end of the test strip.
- Do **NOT** drop the blood directly on the sampling end of the test strip.
- Do **NOT** add or apply a second drop of blood. This may cause a false result.
- Do **NOT** hold or shake the meter while it is testing.

Measuring Process



After eight (8) seconds you will hear a second beep sound and your test result will be displayed on the LCD screen.
The Test result will be stored in meter memory automatically (See Viewing the Meter Memory).

NOTE: *The meter will display "0.0 mmol/L" when blood β-ketone test result is less than 0.1 mmol/L.*

Disposing Used Test Strips and Lancets

Use a Strip Ejecting Button located on the right side of the meter to remove the used test strip.
Used test strips should be safely discarded properly according to instructions from your healthcare professional.
Wash your hands thoroughly with soap and water after handling the meter, lancing device or test strips.

IMPORTANT SAFETY INFORMATION

- Used lancets and strips are biohazardous material and can transmit blood-borne diseases. Dispose of used lancets and test strips according to instructions from your healthcare professional.
- Do **NOT** leave the lancets in the lancing device after use, be sure to dispose of it according to instructions from your healthcare professional.
- Do **NOT** re-use the lancet.

⚠**CAUTION**

Keep the test strip, meter, lancing device, lancets and control solution away from all children and pets. Test strips may be a choking hazard.

5. Understanding Your Blood β-Ketone Test Results

Blood β-Ketone Results Interpretation

β-Ketone Results	Interpretation
< 0.6 mmol/L	Normal, please consult with a healthcare professional for your appropriate range of blood β-ketone level.
0.6 ~ 1.5 mmol/L	With blood glucose level greater than 300 mg/dL or 16.7 mmol/L, medical consultation with a healthcare professional is recommended.
> 1.5 mmol/L	With blood glucose level greater than 300 mg/dL or 16.7 mmol/L, consult with a healthcare professional immediately as it indicates a risk of developing Diabetic Ketoacidosis (DKA).

NOTE: *Consult with your healthcare professional for the blood β-ketone range that is appropriate for you.*

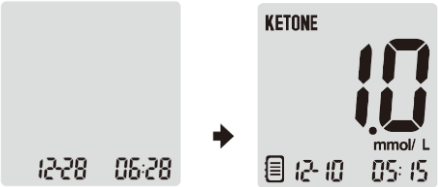
IMPORTANT

- If your test result does **NOT** match how you feel, call your physician or healthcare professional.
- **NEVER** ignore symptoms of high blood β-ketone.
- If you see "HI" displayed, your blood β-ketone level may be above 8.0 mmol/L, repeat the blood β-ketone test using a new test strip. If the meter persists same results, contact your physician or healthcare professional.
- **NEVER** change any treatment without first consulting with your physician or a healthcare professional.
- Hematocrit is the percentage of red blood cells in the blood. Testing outside of the Hematocrit level range of 20~60% may cause inaccurate result. If you do **NOT** know your hematocrit level, consult with your healthcare professional.
- This system is **NOT** for use on patients who are in shock or dehydrated.
- Inaccurate results may occur in severely hypotensive individuals.
- This system is **NOT** for use on critically ill patients.

6. Displaying Stored Test Results

The Medisign ***MediKeto 82 BT*** blood β-ketone meter automatically stores up to five hundred (500) β-ketone test results together with the date and time. The time and date must be set in order to use the memory function (See Set Date and Time).

Display of Test Results



1. Begin with the meter turned off. Press the ⏻ button, you will hear a beep sound and the meter will turn on.
3. The screen will display the date and time. After two (2) seconds, the latest test result is displayed first.
4. Each time you continue to press the > button, the screen will show the test result from the most recent to the oldest. Use the < or > button to switch stored results.

NOTE:

- *After five hundred (500) data entries, every new test results replaces the oldest (first in, first out).*
- *Meter memory test results will **NOT** be erased when battery is removed.*
- *The Meter will automatically turn off after two (2) minutes of non-use.*

7. Downloading Your Test Results to a PC

You can transfer test results from the Medisign ***MediKeto 82 BT*** blood β-ketone meter to a computer. The program can help you to make a report with graphs and tables. To use this feature, you need the Medisign Link Diabetes Management Software and the Medisign Link Cable. For more information, please contact Customer Service.

NOTE: *While the meter is connected to the PC, you are unable to perform a blood ß-ketone test.*

8. Pairing Your Meter

Before Pairing Your Meter

Pairing must be completed between the Medisign ***MediKeto 82 BT*** blood β-ketone meter and your Bluetooth mobile device before your meter can communicate with your mobile device. Both devices must be within ten meter (10 M) range apart of each other in order to sync properly. The meter can be paired with only one smart device at a time. To avoid malfunctions when transferring data, please remove the meter from the list of paired devices before setting up any new pairing.

The Medisign ***MediKeto 82 BT*** blood β-ketone meter is compatible with:

- Android device (requires OS 4.3 or higher)
- Apple iOS device (requires iOS 8.0 or higher)
- Mobile devices compatible with Bluetooth 4.0

How to Pair Your Meter

1. Press the ⏻ button to turn on the meter.
2. If your mobile device is set to search for other devices, you can find the Medisign ***MediKeto 82 BT*** blood β-ketone meter name along with the serial number displayed.
3. Select or tap the name of the meter displayed you wish to connect.
4. If your mobile device and the meter are successfully connected, the ᛒ will be shown on the meter display.
5. If you are prompted to pair your mobile device after connecting, you may need to enter the pairing password on the display. The pairing password is “000000” (six zeros).

About Bluetooth

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept any interference received, including interference that may cause undesired operations.

9. Cleaning Your Meter

Wash and dry your hands before use to prevent damage of the meter and test strips. The meter should be cleaned with a soft cloth or paper towel slightly dampened with one of these cleaning solutions:

- 70% isopropyl alcohol
- Mild dishwashing liquid mixed with water
- 10% household bleach solution made on the day

After cleaning, allow the meter to dry completely in a cool place away from direct sunlight.

IMPORTANT

- The meter must be turned off when you clean the meter.
- Clean your Medisign ***MediKeto 82 BT*** blood β-ketone meter once per week at a minimum.
- Do **NOT** get water inside the meter. **NEVER** immerse the meter or hold it under running water or spray any cleaning solution directly onto the meter.
- Do **NOT** use glass cleaners or household cleaners or corrosive liquid (e.g. Benzene, Acetone) on the meter.
- Do **NOT** try to get moisture on the test strip, test strip slot or serial port.
- Do **NOT** destroy, repair or transform the system at any time. If the equipment is used in a manner NOT specified by the manufacturer, the protection provided may be impaired.
- Handle the meter with care – severe shock, such as dropping the meter, could damage the electronics.
- Squeeze the excess liquid from the cloth before you wipe the meter.

Sign of Deterioration

The list of things you should look for as signs of deterioration after cleaning include:

- Control Solution results is out of the range
- Clouding of the LCD display
- Corroding of the plastic housing or buttons
- Malfunction of any meter function

If these signs of deterioration are noted, do **NOT** use the meter and contact Customer Service.

10. Screen Messages and Troubleshooting

Screen Messages

This section explains the display screen messages and error messages you may encounter when using your Medisign ***MediKeto 82 BT*** blood β-ketone meter and test strips. If your meter is still **NOT** working after you have followed the troubleshooting instructions, contact Customer Service.

What you see	What it means	What you should do
Er 1 12:28 06:28	The meter has detected a problem with the test strip. The test strip is either used or damaged.	Repeat the test with a new test strip.
Er2 12:28 06:28	The blood sample was applied to the test strip before the blood symbol appeared on the screen.	Remove and discard the test strip and insert a new one. Apply blood to the test strip after the blood symbol appear on the screen.
Er3 12:28 06:28	The ambient temperature is too high or low to test.	Put the meter and test strips in a location within the operating temperature range (10 ~ 40℃) for at least twenty (20) minutes and repeat the test. Do **NOT** raise or lower the meter temperature artificially.
Er4 12:28 06:28	Not enough blood sample was drawn into the test strip.	Repeat the test with a new test strip. If error persists, please contact Customer Service.
Er5 12:28 06:28	The wrong test strip has been inserted into the meter.	Make sure you are using the Medisign ***MediKeto 82*** blood β-ketone test strip and repeat the test.
Er6 12:28 06:28	There is an internal error with the meter.	Please contact Customer Service.
Er7 12:28 06:28	Temperature is out of the operating range during the test.	Repeat the test under the stable temperature condition.
Er8 12:28 06:28	The test strip is flicked during the test.	Repeat test with a new test strip. Please do **NOT** touch the test strip during the test. If error persists, contact to Customer Service.
KETONE HI mmol/L 12:28 06:28	Blood β-ketone test result is higher than 8.0 mmol/L.	Repeat the test with a new test strip. If the result is still “HI”, contact your physician or healthcare professional.

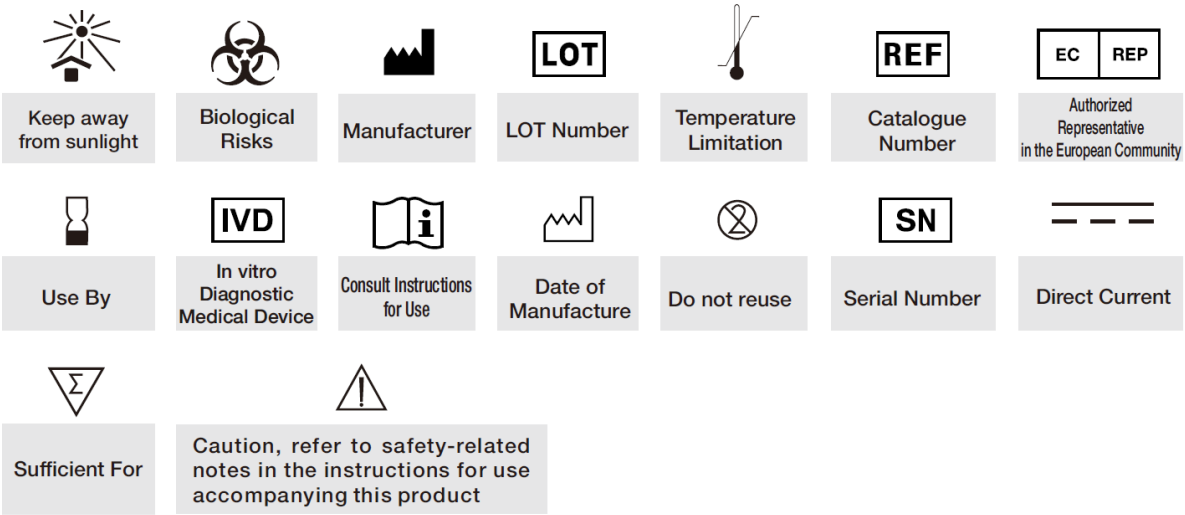
Troubleshooting

What is happening	What you should do
The meter does **NOT** work after the blood is applied.	• Make sure that the test strip is insert into the test strip slot completely. • See if the test strip is covered in debris or lint. • Make sure the blood is applied to the test strip correctly. • Make sure the test strip is inserted correctly and repeat the test.
The test result is abnormal.	• See if the test strip is covered in debris or lint. • Check if the test strip is within the validity period. • Make sure the test strip has **NOT** been stored out of its vial. • Make sure the test strip has **NOT** been used before. • Make sure the code on the meter display matches with the test strip code.
The thermometer symbol appears on the screen.	• Put the meter and test strips in a location within the operating temperature range (10 ~ 40℃) for at least twenty (20) minutes and repeat the test. Do **NOT** raise or lower the meter temperature artificially. • If the thermometer symbol is constantly showing, contact Customer Service.
The meter does **NOT** work after the test strip is inserted.	• Make sure the test strip is completely inserted into the test strip port. • Make sure the batteries are inserted correctly, with the + sign facing upwards.

11. System Specifications

Measuring Range	0.1 ~ 8.0 mmol/L
Measuring Time	8 seconds
Memory capacity	500 test results (include date and time)
Sample Type	Fresh capillary(only fingertip) and venous whole blood
Operating condition	10 ~ 40℃
Sample volume	0.5 μℓ
Screen type	Backlight LCD
Dimensions (mm)	90 (L) x 53 (W) x 18 (H)
Weight	Approximately 52g (with batteries)
Power supply	DC 3V (CR2032) Lithium Battery
Data Output	Bluetooth, USB Data Transfer Cable
Wireless Frequency	2.4 GHz Band

12. Symbols



13. Disposing of the Meter

IMPORTANT SAFETY INFORMATION

Objects (e. g. the meter) which had been in contact with blood potentially bear the risk for infectious diseases. Please dispose these materials according to local regulations for disposal of contaminated medical devices.

Please dispose of the contaminated meter – after removing the battery – according to the regulations applicable to your country. For information about correct disposal, please contact your local council or authority. The meter falls within the scope of European Directive 2012/19/EU (Directive on waste electrical and electronic equipment (WEEE)).

14. Additional Supplies

The following supplies and accessories are available from your supplier, for more information contact Customer Service.

- Medisign Link Cable
- Medisign Link Diabetes Management Software
- Medisign ***MediKeto 82*** blood β-ketone test strips
- Medisign Ketone Control Solution
- Medisign Ketone Check Strip

15. Product Warranty

The Medisign ***MediKeto 82 BT*** blood β-ketone meter is warranted to be free of defects in workmanship and materials for a period of three (3) years from the date of purchase. Manufacturer's liability for warranty claims is limited to repair or replacement, and in no event shall manufacturer be liable for indirect or consequential damages, or for any loss arising from misuse, improper use, abuse, neglect, unauthorized repair or modification.

This warranty is void and of no force and effect in the event of product misuse, improper use, abuse, neglect, unauthorized repair or modification. This warranty specifically excludes the Medisign ***MediKeto 82*** blood β-

ketone test strip and the Medisign Ketone Control Solution.

THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY TO THE EXCLUSION OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ALL OF WHICH ARE WAIVED AND DISALAIMED.

All warranty claims must be directed to Customer Service. This warranty is extended only to the original purchaser of the meter.

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 β-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.
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7. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007'.http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html

FCC Information to User

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

• Reorient or relocate the receiving antenna.
• Increase the separation between the equipment and receiver.
• Connect the equipment into an outlet on a circuit different from that to which the receiver is con-nected.
• Consult the dealer or an experienced radio/TV technician for help.

Caution

Modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Compliance Information : This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.