KT21 BT

Blood Beta-Ketone Monitoring

System User Manual

Introduction

Thank you for choosing the ***KT21 BT*** blood Beta-ketone monitoring system to help monitor your blood Betaketone levels. The ***KT21 BT*** blood Betaketone monitoring system is designed to be accurate and easy to use. This user manual contains all the information needed to use and maintain the ***KT21 BT*** blood Betaketone 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 ***KT21 BT*** blood β-ketone meter as well as the corresponding accessories regularly.
- Healthcare Professionals performing blood Beta-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.
- 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** reuse a lancet.
- If you have taken the cap off 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.
- The control solution contains agents that may be harmful if swallowed or applied to the skin or eyes. Do **NOT** drink the control solution, as it is meant to be used on the test strips only.

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 ***KT21 BT*** blood Beta-ketone monitoring system is intended to be used for the quantitative measurement of Beta-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

Beta-Ketone in the blood sample reacts with enzyme (beta-hydroxybutyrate dehydrogenase) on the test strip respectively. This reaction produces a harmless current and the ***KT21 BT*** blood Beta-ketone meter measures the current, and calculates the Beta-ketone level and displays the result. The strength of the current is dependent on the amount of Beta-ketone in the blood sample.

Important Information for the System

- Before using the ***KT21 BT*** blood Beta-ketone monitoring system, please read this manual carefully.
- Use this system only for blood Beta-ketone test.
- The ***KT21 BT*** blood Beta-ketone meter should be used with the ***MediKeto 81*** blood Beta--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 Beta-ketone.
- If you see "HI" displayed, your blood Beta--ketone level may be above 8.0 mmol/L, repeat the blood Beta-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 Beta-ketone measurement unit on the meter before the test. Use of the wrong blood Beta-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 Beta-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 box, 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.

Important Information for the Control Solution

- Use only the ***MediKeto*** Ketone Control Solution. Other brands of control solutions will produce inaccurate results.
- Shake the 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.
- The range printed on the test strip vial or box is for the control solution only. It has nothing to do with your blood Beta-ketone levels.
- The results obtained from control testing do **NOT** reflect your personal blood Beta-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. You should use fresh capillary, venous whole blood only.
- Do **NOT** put urine on the test strip.
- This system is **NOT** designed for use with neonatal.
- This system is **NOT** for screening or diagnosis of diabetes mellitus.
- Blood Beta-ketone testing must **NOT** use the forearm or palm site. Only use the fingertip for blood Beta-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 vial or 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 ***KT21 BT*** blood Beta--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 *KT21 BT* blood Beta-ketone monitoring system.....7
- Contents of Kit.....7
- *KT21 BT* Blood Beta-Ketone Meter.....7
- Meter Display Screen.....8
- *MediKeto 81* Blood Beta-Ketone Test Strip.....9
- *MediKeto* Ketone Control Solution.....9
- *MediKeto* Check Strip.....9

2. Settings.....10
- Inserting (or Replacing) the Batteries.....10
- Change Settings.....10
- Time and Date.....11
- Acoustic Signal.....11
- Delete Your Test Results.....11

3. Control Solution Testing.....12
- Performing a Control Solution Test.....13
- Performing the Check Strip Test.....14

4. Testing Your Blood Beta-Ketone.....15
- Preparing the Test.....15
- Inserting the *MediKeto 81* Blood Beta-Ketone Test Strip.....16
- Obtaining a Blood Drop.....16
- Applying Blood.....17
- Measuring Process.....17
- Marker function and display.....18
- Disposing Used Test Strips and Lancets.....18

5. Understanding Your Blood Beta-Ketone Test Results.....19
- Blood BetaKetone Results Interpretation.....19

6. Displaying Stored Test Results.....19
- Display of Test Results.....19

7. Downloading Your Test Results to a PC.....20

8. Pairing Your Meter.....20
- Before Pairing Your Meter.....20
- How to Pair Your Meter.....20

9. Cleaning Your Meter.....21

10. Screen Messages and Troubleshooting.....22
- Screen Messages.....22
- Troubleshooting.....23

11. System Specifications.....23

12. Symbols.....24

13. Disposing of the Meter.....25

14. Additional Supplies.....25

15. Product Warranty.....25

1. About the *KT21 BT* blood Beta-ketone monitoring system

Contents of Kit

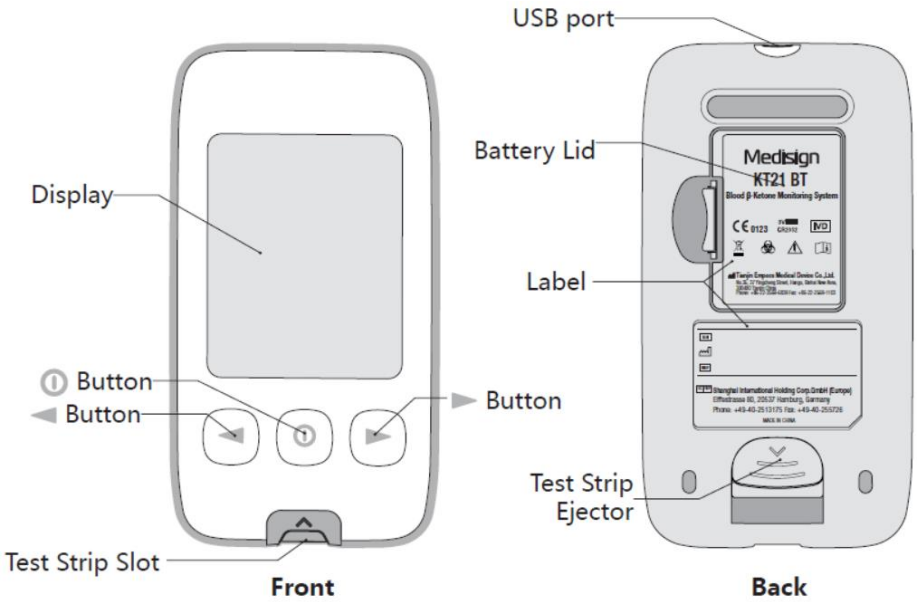
The ***KT21 BT*** blood Beta-ketone monitoring system includes the following items:

- ***KT21 BT*** blood Beta-ketone meter
- ***MediKeto 81*** blood Beta-ketone test strips (10
- Tests) Lancing Device
- Lancets
- Battery (CR2032)
- Carrying Bag
- User Manual

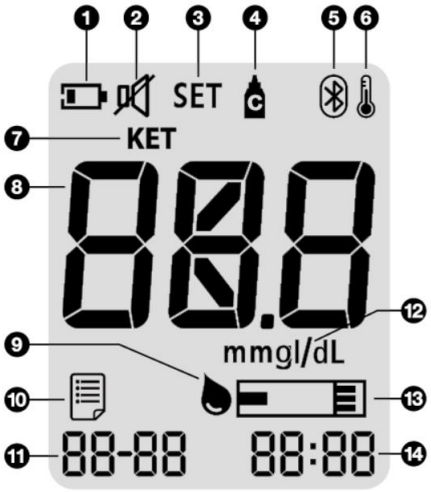
NOTE:

- The ***MediKeto 81*** *blood Beta-ketone test strips (for 10, 25 Tests or 50 Tests), the* ***MediKeto*** *Check Strip, and the* ***MediKeto*** *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.*

KT21 BT Blood Beta-Ketone Meter



Meter Display Screen

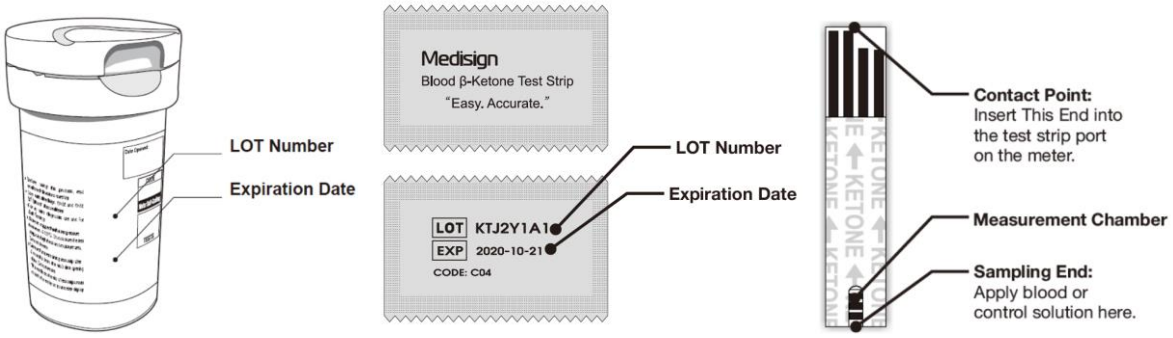


1		Appears when the meter detects low battery power
2		Appears when the sound is set to OFF
3	SET	Segments to display the Set-up mode
4		Symbol to mark the control solution test results
5		Appears when Bluetooth is activated and the meter pairs with a mobile device
6		Appears if the meter is out of operating temperature range
7	KET	Appears when the test strip is inserted
8	88.8	Segments to display test results or error messages
9		Appears when the meter is ready for application of blood or control solution.
10		Appears when test results stored in memory are displayed
11	88-88	Segments to display date and average day
12	mmgl/dL	Segments to display the unit of measurement
13		Appears when test strip is inserted. Blinks when test strip is removed during the meter is on.
14	88:88	Segments to display hour and minute of tests

IMPORTANT

Be sure to check the blood Beta ketone measurement unit on the meter before the test. Use of the wrong blood Beta 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 Beta ketone measurement units.

MediKeto 81 Blood Beta-Ketone Test Strip



MediKeto 81 **Blood BetaKetone Test Strip Vial**	*MediKeto 81* **Blood Beta Ketone Test Strip Foil Packet**	*MediKeto 81* **Blood Beta-Ketone Test Strip**

• The expiration date of the ***MediKeto 81*** blood Beta ketone test strip can be found on the vial or the foil packet.

IMPORTANT

- The ***KT21 BT*** blood Beta-ketone meter should be used with the ***MediKeto 81*** blood Beta-ketone test strips.
- Before using, please check the test strip expiration date on the box, 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.

MediKeto Ketone Control Solution

The ***MediKeto*** Ketone Control Solution is the standard blood Beta ketone concentration solution required to perform a control test (See Control Solution Testing).
The ***MediKeto*** 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 ***MediKeto 81*** blood Beta-ketone test strips.

MediKeto Check Strip

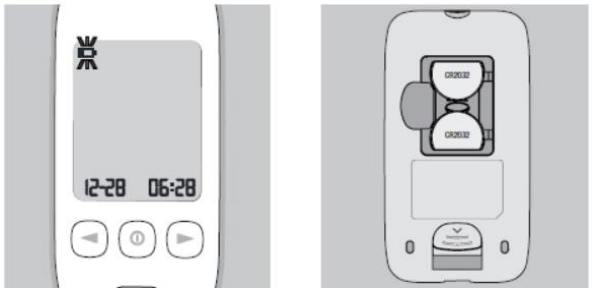
The ***MediKeto*** Check Strip verifies whether the ***KT21 BT*** blood Beta-ketone meter is working

properly.

2. Settings

Inserting (or Replacing) the Batteries

The batteries need to be inserted before using your ***KT21 BT*** blood glucose 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 screen. Change the batteries immediately when this occurs.



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:

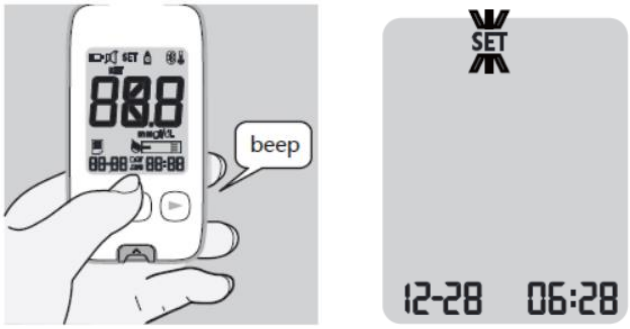
- *The meter can also be used with a single battery. If you install two (2) batteries, you can use it for a longer period.*
- *Whenever replacing the batteries, you need to reset the current date and time. However, test results stored will **NOT** be deleted.*

Change Settings

To change the device's settings, press the button and hold for more than 3 seconds until the symbol SET is displayed.

When adjusting the settings, SET is continuously shown on the main display. Use the button to switch between the setting options.

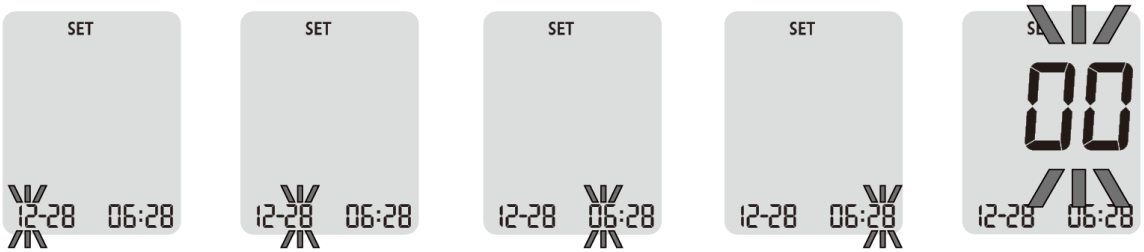
The following pages show the setting options of your blood Beta-ketone meter.



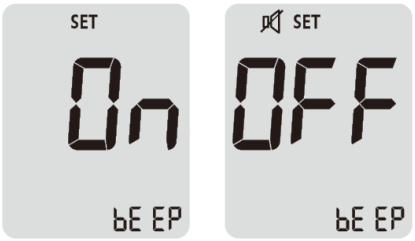
NOTE: *You can exit the device's settings mode at any time by holding the button for longer than 3 seconds.*

Time and Date

Press the button to set the hours, minutes, year, month and day one after another. With the left or right 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 left or right 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 glucose measurements.*

Delete Your Test Results

When you enter the Delete Mode by press the button, the meter shows “dEL” on the display then, “no” message will be prompted shortly after. You can toggle the message “no” and “yes” by pressing the left or right button. If you want to keep your all test results, press the button while “no” message on the display. On the other hand, when you press the button while “yes” message on the display, then all the test results will be deleted from the meter.

3. Control Solution Testing

The purpose of the control solution testing is to validate that the ***KT21 BT*** blood Beta-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 ***MediKeto*** 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 test strip vial is left open.
- 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.

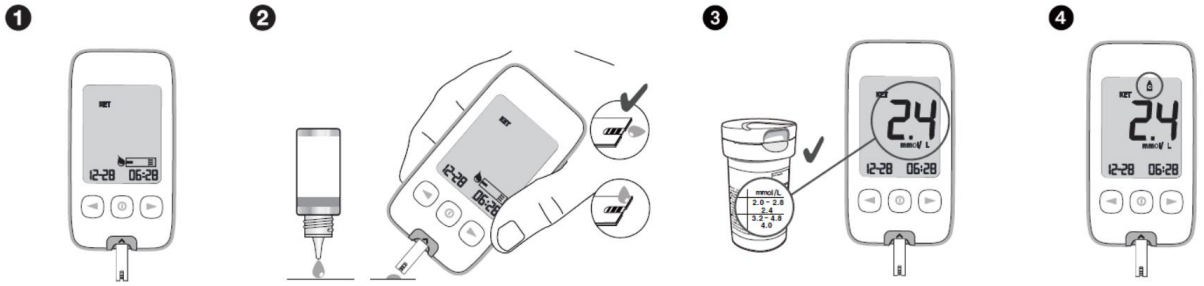
⚠**CAUTION**

The control solution contains agents that may be harmful if swallowed or applied to the skin or eyes. Do **NOT** drink the control solution, as it is meant to be used on the test strips only.

IMPORTANT

- Use only the ***MediKeto*** 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.
- 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



NOTE: *The control solution test range on the picture above is for the example only. The test range can be different for each test strip batch.*

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 of the test strips. If the two code numbers do **NOT** match, contact Customer Service. When the blood drop symbol appears on the screen, shake the control solution vial well.
2. Remove the control solution 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.
   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.

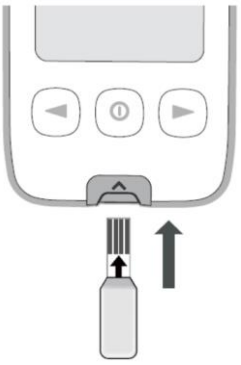
3. When the test strip measurement chamber is full, the meter will beep. The meter will count down from eight (8) seconds and then show the control test result. Make sure the test result on the screen is between the ranges printed on your test strip box or vial.
4. You can flag the control solution symbol by pressing the left or right button with the test result on the display and the test strip still in the meter.
5. Press the button to permanently save the selected marker and the device automatically switches off.
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 Beta-ketone 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 Beta ketone levels.
- The results obtained from control testing do **NOT** reflect your personal blood Beta 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 Beta ketone.
  - Make sure you are using the ***MediKeto*** Ketone Control Solution.
  - Make sure the testing environment is between 10 ~ 40°C.
  - Make sure the ***MediKeto*** 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 ***MediKeto*** 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 ***MediKeto*** Check Strip, please contact Customer Service.

4. Testing Your Blood Beta-Ketone

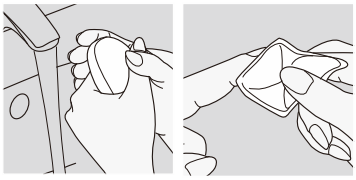
IMPORTANT SAFETY INFORMATION

- 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 ***KT21 BT*** blood Beta-ketone meter as well as the corresponding accessories regularly.
- Healthcare Professionals performing blood Betaketone 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.

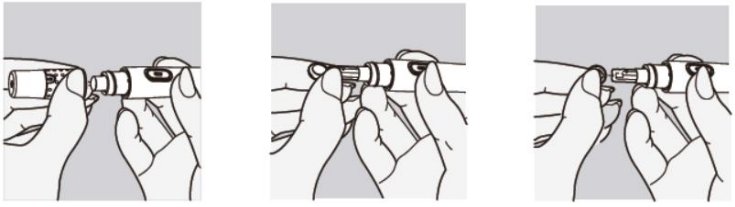
⚠**CAUTION**

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

Preparing the Test



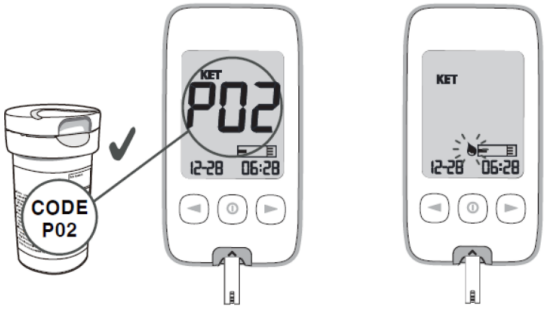
1. The easiest way to collect a drop of blood is to wash your hands with warm water and soap first. This promotes the blood circulation in the fingertips. Then dry your hands properly. The puncture site can alternatively be wiped with an alcohol- soaked swab. Please ensure that the site is completely 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 *MediKeto 81* Blood Beta-Ketone Test Strip



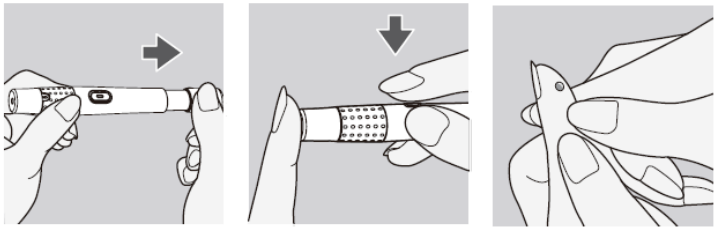
NOTE: *The code number on the picture above is for the example only. The code number can be different for each test strip batch.*

1. Insert a test strip to turn on the meter automatically. Make sure it is inserted completely without bending the test strip. **KET** will appear on screen if the ***MediKeto 81*** blood Betaketone 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 Betaketone 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. If you have your own lancing device, please follow your lancing device instruction for use.*

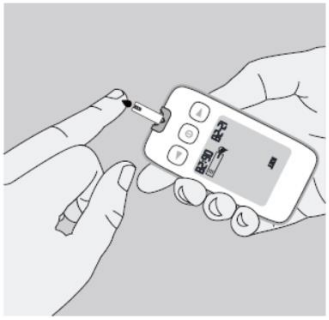
IMPORTANT SAFETY INFORMATION

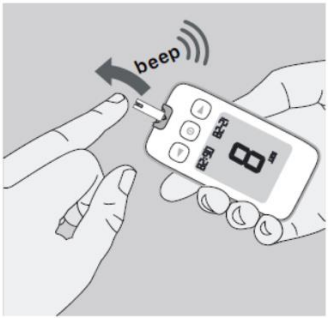
If you have taken the cap off the lancet and the lancet has fallen to the ground, do **NOT** use it. Make sure you dispose of it and replace it with a new lancet.

IMPORTANT

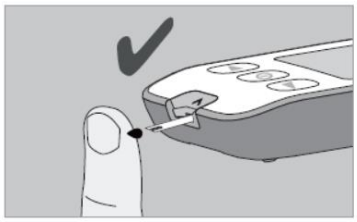
- Do **NOT** squeeze excessively around the puncture site when you produce a drop of blood.
- If alcohol wipes are used to disinfect the fingertip, make sure the fingertip is completely dry before obtaining the blood sample.
- Blood Betaketone testing must **NOT** use the forearm or palm site. Only use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

Applying Blood





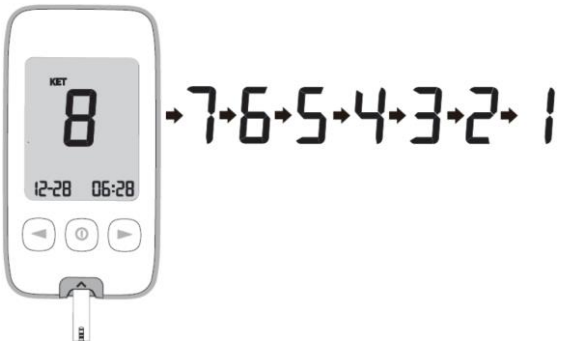
Place your finger on the tip of the test strip. Ensure that the blood is **NOT** applied from above.
The measurement chamber of the test strip draws the blood of your finger automatically. Your finger should remain still until the measuring chamber is completely filled and you hear the "beep" sound.



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 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 Display of Test Results).

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

Marker function and display

After testing, press the left or right button to select one of the following markers.

C	Test was performed with control solution.

Press the button to permanently save the selected marker and the device automatically switches off.

NOTE:

- *If you press the left or right button and don't confirm your selection within 10 seconds, it will be confirmed automatically.*
- *Marking control solution tests with this marker is important since otherwise your average values and statistical evaluations would be compromised.*

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

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** reuse the lancet.

5. Understanding Your Blood Beta-Ketone Test Results

Blood BetaKetone Results Interpretation

If your Betaketone result between 1.5 and 3.0 mmol/L may indicate development of a problem that could require medical assistance. Follow your healthcare professional's instructions. If your Betaketone result is higher than 3.0 mmol/L, contact your healthcare professional promptly for assistance you may be at risk of diabetic ketoacidosis (DKA).

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

Reference:

Rewers A. Current controversies in treatment and prevention of diabetic ketoacidosis. *Adv Pediatr*. 2010;57(1):247-267**.**

IMPORTANT

- If your test result does **NOT** match how you feel, call your physician or healthcare professional.
- **NEVER** ignore symptoms of high blood Betaketone.
- If you see "HI" displayed, your blood Betaketone level may be above 8.0 mmol/L, repeat the blood Betaketone 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 ***KT21 BT*** blood Beta-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.
2. The screen will display the date and time. After two (2) seconds, the latest test result is displayed first.
3. 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.
4. Press button to turn off the meter.
5. The meter will automatically turn off after two (2) minutes of non-use.

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.*

7. Downloading Your Test Results to a PC

You can transfer test results from the ***KT21 BT*** blood Beta-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.

Before you download the test result data from the meter to your PC, you have to connect the meter to your PC according to the following steps:

1. Make sure that you have installed Medisign Link Software on your computer.
2. Make sure that your meter is turned off.
3. Insert the rectangular cable end into your computer's USB port.
4. Insert the round cable end into the meter data port, located at the bottom of the meter.
5. When the meter is turn on, "PC" will be shown on the meter. The communication between the meter and your PC is ready.

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

8. Pairing Your Meter

Before Pairing Your Meter

Pairing must be completed between the ***KT21 BT*** blood Betaketone 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 ***KT21 BT*** blood Betaketone 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 ***KT21 BT*** blood Betaketone 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 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).

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 ***KT21 BT*** blood Betaketone 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 ***KT21 BT*** blood Beta-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 test strip was used or applying sample to the test strip before inserting it into the meter or the test strip is damaged.	Repeat the test with a new test strip.
Er2 12-28 06:28	The sample was applied before the meter was ready to test.	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.	The temperature should be 10 ~ 40°C. Move the meter and test strip to an area that is within the temperature range to perform the test. Wait about twenty (20) minutes or until the meter has reached the proper range and retest. Do **NOT** raise or lower the meter temperature artificially.
Er4 12-28 06:28	The error could be caused by one of the following: • Not enough sample was applied into the test strip. • The sample was improperly applied. • The test strip was moved during the test.	Repeat the test with a new test strip using an enough sample. Please do not touch the test strip during the test. 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 ***MediKeto 81*** blood Beta-ketone test strip and repeat the test.
Er6 12-28 06:28	There is a problem with the meter.	Please contact Customer Service.
KET HI mmol/L 12-28 06:28	Blood **Beta**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	0.0 ~ 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	LCD (Backlight optional)
Dimensions (mm)	103 (L) x 55 (W) x 16.5 (H)
Weight	Approximately 72g (with batteries)
Power supply	DC 3V (CR2032) Lithium Battery
Data Output	Bluetooth, USB Data Transfer Cable
Wireless Frequency	2.4 GHz Band

12. Symbols

	Keep away from sunlight
	Biological risks
	Manufacturer
LOT	LOT number
	Temperature limitation
REF	Catalogue number
EC REP	Authorized Representative in the European Community
	Use by
IVD	In vitro diagnostic medical device
	Consult instructions for use
	Date of manufacturer
	Do no reuse
SN	Serial number
	Direct current
	Sufficient for
	Caution, refer to safety-related notes in the instructions for use accompanying this product

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.

- ***MediKeto 81*** blood Beta-ketone test strips
- ***MediKeto*** Ketone Control Solution
- ***MediKeto*** Check Strip
- Medisign Link Cable
- Medisign Link Diabetes Management Software

15. Product Warranty

The ***KT21 BT*** blood Beta-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 ***MediKeto 81*** blood Beta-ketone test strip and the ***MediKeto*** 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. Rewers A. Current controversies in treatment and prevention of diabetic ketoacidosis. *Adv Pediatr*. 2010;57(1):247-267.

CE 0123

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EC REP

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Phone: +49-40-2513175 Fax: +49-40-255726

Rev.06.08.21

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 i 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.

Product Description

Operating Frequency: 2402-2480 MHz
RF Output power: -1.59 dBm
Antenna Type/Gain: PCB Antenna / -4.34 dBi
Rated Supply Voltage: DC 3.0V