

Medisign MM1100 BT Blood Glucose Monitoring System User Manual

Call Customer Service Toll-Free
24 hours a day, 7 days a week
1-888-885-6677
or visit our website www.empecs.com

Manufactured by:
Tianjin Empecs Medical Device Co.,Ltd.
No.35 and 37, Yingcheng Street, Hangu,
Binhai New Area, 300480 Tianjin China

Read this User Manual carefully before you start the test and do a quality control test. If you have any questions about the control test consult with your healthcare professional. Confirm the measuring unit on the display is correct with every test result.

Sign of Trouble

If you are experiencing any of the issues below, call customer service at 1-888-885-6677.

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

If you encounter any issues including the ones mentioned above, call customer service at 1-888-885-6677.

Important Safety Instruction

- Blood glucose meters are at high risk of contamination with blood-borne pathogens such as Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV). Transmission of these viruses from user to user has been documented due to contaminated blood glucose devices. Accordingly, cleaning and disinfecting meters between users can prevent the transmission of these viruses through indirect contact.
- The meter and lancing device are for single patient use. Do not share them with anyone including other family members. Do not use on multiple patients.
- All parts of the kit are considered as biohazards. The system may transmit infectious diseases, even after it has been cleaned or disinfected.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person.
- References
 1. FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Blood Pathogens: Initial Communication (2010)
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
 2. CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses a Risk for Transmitting Blood-borne Pathogens (2010)
<http://www.cdc.gov/injectionsafety/Fingertick-DevicesBGM.html>

Contents

■ About Your New System	
Welcome	01
Intended Use	01
Application	02
Test Principle	02
Special Features	03
Usage and storage	04
Important Information	05
System Components	09
■ Testing Your Blood Glucose	
Disinfection Before test	13
Performing a Blood Glucose Test	14
Flagging Test Results	22
Handling the Used Test Strips	23
Alternate Site Testing (AST)	24
■ Meter Setup, Memory and Downloading	
Setting up Your Meter	28
Reviewing Test Results	28
Downloading Test Results to a PC	34
■ Pairing Your Meter	
How to Pair Your Meter	37
■ Control Test	
Performing a Control Test	40
Understanding Control Test Results	44
■ Maintenance and Troubleshooting	
Cleaning and Disinfecting	45
Replacing the Batteries	50
Screen Messages	52
Troubleshooting	56
■ Technical Information and Warranty	
Specifications	58
Warranty	60
Disposing of your Meter	61
Additional Supplies Available	63

About Your New System

Welcome

Thank you for selecting the Medisign MM1100 BT Blood Glucose Monitoring System. This user manual is designed to provide you with information on how to use the Medisign MM1100 BT Glucose Monitoring System. Follow the instructions carefully that are detailed in this manual. Before using your monitoring system for the first time, please read this manual carefully and If you have any questions, contact Customer Service at 1-888-885-6677, anytime-24 hours a day. You can also obtain information at www.empecs.com.

Intended Use

Medisign MM1100 BT Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm, and forearm by a single patient (lay user) as an aid in the management of diabetes. It is intended for self testing by persons at home, for single patient use only, and should not be shared.

It is intended for use outside the body (in-vitro diagnostic use only) and not for the diagnosis of or screening of diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly).

Application

Medisign MM1100 Blood Glucose Test Strips are for in-vitro diagnostic use and for self testing only. The Medisign MM1100 BT Blood Glucose Meter is not a substitute for your physician or Healthcare Professional. Use the Medisign MM1100 BT Blood Glucose Meter in conjunction with your Healthcare Program.

Test Principle

Glucose in the blood sample reacts with glucose oxidase on the test strip and a harmless electrical current is produced. The strength of these currents change with the amount of glucose in the blood sample and the Medisign MM1100 BT Blood Glucose Meter automatically interprets this reaction.

Glucose measurements are reported as plasma equivalents. This system uses plasma equivalent methodology. Results that use a plasma equivalent method are approximately 11% higher than those obtained with whole-blood equivalent test strips.

Special Features

- Accurate result in 5 seconds using only 0.5 μ l blood sample.
- The Medisign MM1100 BT Glucose Meter identifies the test strip code automatically.
- Stores up to 300 test results.
- Blood glucose measurement units are pre-set in mg/dL.

Usage and Storage

- Before using your monitoring system, please place it in the environment of the system's normal operating temperature range of 50-104 °F for about twenty (20) minutes.
- Do not allow dirt or dust into the test strip port in order to avoid affecting the monitoring system's accuracy.
- Do not attempt to repair or alter your monitoring system.
- Do not put the monitoring system near any electromagnetic field. (e.g. TV, microwave oven, mobile phone)
- Handle your monitoring system with care.
- Keep away from direct sunlight and humid conditions.
- Please use a soft cotton cloth to wipe the system.
- Do not use a corrosive product (e.g. Benzene, Acetone) to clean your monitoring system.

Important Information

- Make sure to use your test strip immediately after retrieving it from the vial, be sure to keep the test strip vial closed tightly at all times.
- For the most accurate results, make sure your hands are clean and dry before removing the test strips from their vial.
- Do not touch test strip slit.
- Do not use test strips that have expired, using expired test strips may cause inaccurate test results.
- Never reuse a test strip that has had either blood or control solution applied. The Medisign MM1 100 Test Strip is for single use only.
- This product is not recommended for pregnant women, newborns or if you are severely dehydrated.
- Before the test you must make sure that the code number displayed on the meter matches the code number on the test strip vial.
- Keep your Medisign MM1 100 BT Blood Glucose Meter, lancing device, lancets and control solutions out of reach of children or pets.

- Be sure to check the glucose measurement unit on the meter before the test.
 - This meter is preset to mg/dL.
 - mg/dL is the unit of measurement used in the US.
- Make sure you close the test strip vial is closed tightly and store at indoor area between 39 ~ 86°F, 10~90%RH. Do not freeze.
- Keep test strips away from direct sunlight and heat.
- Use this system only for blood glucose test.
- Before using the Medisign MM1 100 BT Blood Glucose Monitoring System, please read this manual carefully.
- The meter and test strips should be handled at the same temperature.
- For accurate test results, keep the Medisign MM1 100 BT Blood Glucose Monitoring System operating temperature at a range between 50-104°F for more than twenty (20) minutes before testing.

- Do not use any anticoagulants or preservatives other than heparin when collecting capillary blood into test tubes.
- Be sure to clean and disinfect your Medisign MM1100 BT Blood Glucose Meter regularly.
- Do not reuse the test strips, test strips are single use only.
- You may use this system at altitude up to 10,000 feet.
- Clean and disinfect your Medisign MM1100 BT Blood Glucose Meter at least once per week.
- The Medisign MM1100 BT Blood Glucose Monitoring System is for testing outside of the body (in-vitro diagnostic use).
- Inaccurate results may occur for individuals or patient in shock.
- Inaccurate results may occur for individuals experiencing a hyperglycemic-hypersmolar state with or without ketosis. Critically ill patients should not be tested with this blood glucose meter.
- Interferences: Acetaminophen, salicylates, uric acid, ascorbic acid (vitamin C) and other interferent substances in normal blood or normal therapeutic concentrations do not significantly affect results, however abnormally high concentrations in blood may cause inaccurate results.

- Testing under out of the specification range may cause inaccurate results.
- Patients undergoing oxygen therapy may yield false low results.
- Lipemic samples (triglycerides) in excess of 1,500 mg/dL may produce elevated results.
- Hematocrit is the percentage of red blood cells in the blood. HCT levels of 30-55% do not affect glucose measurements with this meter. If you do not know your hematocrit level, consult with your healthcare professional.
- This test strip is not for use with arterial, venous, neonatal, serum or plasma samples.
- Testing out of HCT level range of (30~55%) and recommended storage conditions may cause inaccurate results.
- Dispose of used test strips and lancets according to instructions from your healthcare provider.

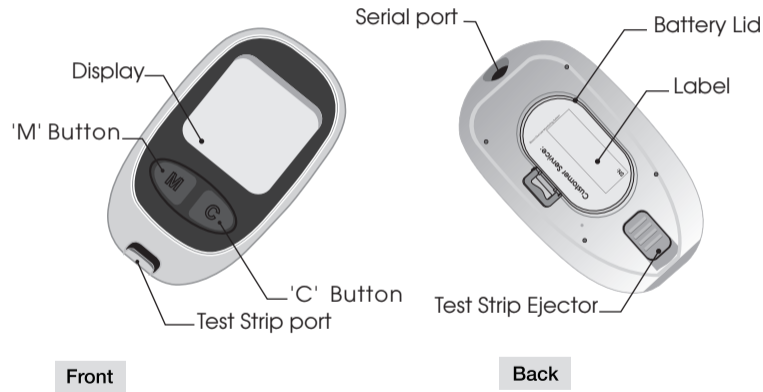
CAUTION: Use only Medisign MM1100 Test Strips with your Medisign MM1100 and Medisign MM1100 BT Blood Glucose Meters.

The Complete Medisign MM1100 BT Blood Glucose Monitoring System

The Medisign MM1100 BT Blood Glucose Monitoring System includes the Medisign MM1100 BT Meter, Ten(10) Medisign MM1100 Test Strip, Lancing Device, Lancets, Carrying Bag, User Manual, Warranty Card, (2) 3.0 Volt CR2032 Lithium Batteries and Logbook.

Medisign MM1100 test strips and Medisign Glucose Control Solution can be provided by contacting your supplier, or for additional information you can contact Customer Support at 1-888-885-6677.

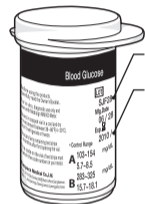
Medisign MM1100 BT Blood Glucose Meter



Front

Back

Medisign MM1 100 Blood Glucose Test Strip



Lot Number
Expiration Date

Test Strip Vial

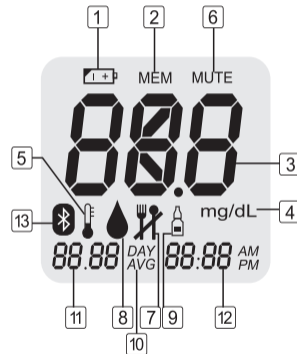


Sample Channel

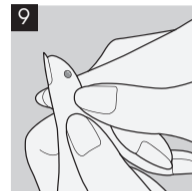
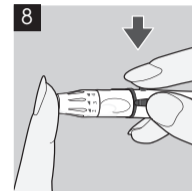
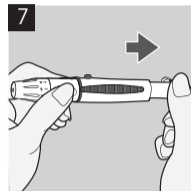
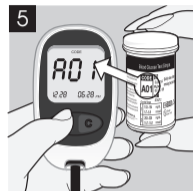
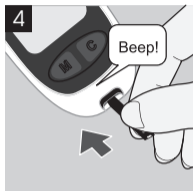
Medisign MM1 100 Blood Glucose Test Strip

- Use Medisign MM1 100 Blood Glucose Test Strips with the Medisign MM1 100 and Medisign MM1 100 BT Blood Glucose Meter.
- Check the expiration date of your test strips before using.
- Write the opening date of the new test strip vial in order to avoid using any expired products.

Explanation of Display



1		Low Battery Warning
2	MEM	Stored Test Results
3	000	Test Results
4	mg/dL	Unit of Measurement
5		Temperature Error
6	MUTE	No Beep
7		Pre meal / Post meal Mark
8		Ready to Test
9		Control Solution
10	AVG	Average Result
11	88.88	Month / Date
12	88:88	Time
13		Bluetooth® (wireless RF on)

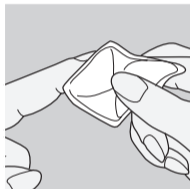


4. Insert a test strip to turn on the meter. Make sure it is inserted completely without bending the test strip.
5. The meter identifies the code number automatically. Compare the code number displayed on the LCD with the code number shown on the test strip vial. If they do not match try again with an another test strip. If the problem persists contact customer support at 1-888-885-6677.
6. When the blood symbol appears, you can proceed with your test.

7. 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.
8. Hold the lancing device firmly against your finger. Press the release button.
9. Gently squeeze your finger to assist the flow of blood. Do not squeeze excessively on the puncture site.

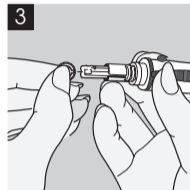
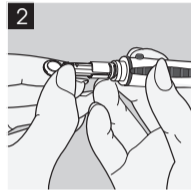
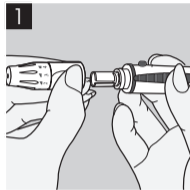
Testing Your Blood Glucose

Disinfect Before Testing



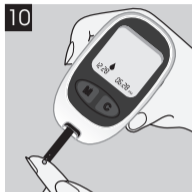
- Before testing, wash your hands with soap and water and dry thoroughly.
- Use an alcohol prep pad to wipe the area before testing.
- Wait until the alcohol dries completely.

Performing a Blood Glucose Test



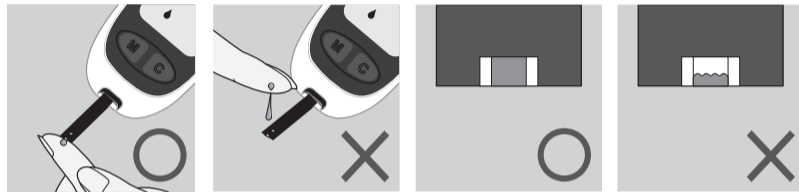
1. Remove your lancing device cap.
2. Install the new lancet into your lancing device.
3. Remove the protective cap from the lancet. Replace the lancing device cap.

NOTICE: Refer to the lancing device instruction for additional detailed information. The lancing device instruction depicted in this manual is for most universal lancing devices.



10. Hold the tip of the test strip to the drop of blood, the test strip will automatically draw the blood into the test strip. When the test strip has enough blood the meter will beep and count down from five seconds. After five seconds your test result will appear.

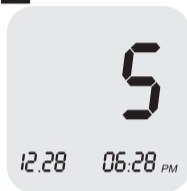
NOTICE: When the blood sample is not sufficient, the display screen will show the message of "Er 4"(Please refer to error messages in this manual.)



CAUTION:

- Do not drop the blood directly on the end of the test strip.
- 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.
- Inaccurate results may occur for individuals or patient in shock. Inaccurate results may occur for individuals experiencing a hyperglycemic-hypersmolar state, with or without ketosis. Critically ill patients should not be tested with a blood glucose meter.

11



12



11. The test result will appear after the meter counts down from five (5) seconds. Keep the meter still while it is counting down.
12. After five (5) seconds you will hear a second beep sound and your test result will be displayed on the LCD screen. You can remove the test strip by pushing the test strip ejector on the back of the meter and the meter will shut off automatically.

NOTICE:

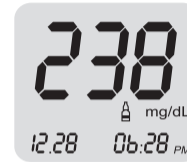
If the test result is abnormal, please retest with a new test strip. If the test result also has a problem, please refer to the Troubleshooting section in this manual.

CAUTION:

- Do not leave the lancet in the lancing device after use, be sure to dispose of properly.
- 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.
- Always dispose of the used lancets in a biohazard container.
- Keep your Glucose Meter, test strips, control solution, lancing device and lancets out of reach of children or pets at all times.
- Do not reuse lancets, lancets are for single use only.

- Blood glucose meters are at high risk of becoming contaminated with blood-borne pathogens such as Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV). Transmission of these viruses from resident to resident has been documented due to contaminated blood glucose devices. Accordingly, cleaning and disinfecting of meters between resident uses can prevent the transmission of these viruses through indirect contact.
- The meter and lancing device are for single patient use. Do not share them with anyone including other family members. Do not use on multiple patients.
- All parts of the kit are considered bio hazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- User should wash their hands thoroughly with soap and water after handling the meter, lancing device or test strips.
- Please see the section on "Cleaning and Disinfection" to clean and disinfect the meter or lancing device.

Flagging Test Results

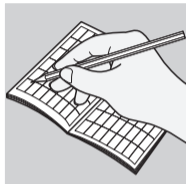


If you want to flag pre-meal, post-meal or control solution readings press the 'M' Button after your test result is displayed. The icon for post-meal (🍴), will be displayed on your screen. Press the 'C' Button to toggle between pre-meal (🍴), post-meal (🍴) and control solution (🧴). After you have identified the activity you would like to flag simply remove the test strip. (see explanation of display on page 11)

NOTICE:

Control Solution Test results are not included in the 14-day average.

Handling Used Test Strips



1. Be sure to document your test result by writing it in your logbook after your test. You can then take your logbook to your physician who can review your results.
2. Use the test strip ejector located on the back of the meter to remove the used test strip.
3. The meter will turn off automatically once the test strip is removed.
4. The used test strip should be handled carefully and disposed of properly.

Alternate Site Testing

Contact your Healthcare Professional before using any alternative sites to test your blood glucose.

- Alternative site results may be different from fingertip results when glucose levels are changing rapidly (e.g., after a meal, after taking insulin, or during or after exercise).
- Use alternative site testing only two hours or more after taking insulin, two hours or more after a meal, two hours or more after exercise.
- Do not use alternative site testing if you are aware that your glucose level is not as stable as usual, or if you think you may have hypoglycemia (low blood glucose) hyperglycemia (high blood glucose), or you think your blood glucose may be rising or falling rapidly.
- Do not use alternative site testing if your alternative site testing results do not match the way you feel.
- AST measurements should never be used to calibrate continuous glucose monitors (CGM).
- AST measurements should never be used in insulin dosing calculations.

Do not rely on test results at an alternative sampling site, but use samples taken from the fingertip, if any of the following applies:

- you think your blood sugar is low.
- you are not aware of symptoms when you become hypoglycemic.
- the site results do not agree with the way you feel.
- after a meal.
- after exercise.
- during illness.
- during times of stress.

CAUTION:

- Never change your treatment without first consulting your Physician or a Healthcare Professional.
- Never ignore symptoms of high or low blood glucose.
- If your blood glucose does not match how you feel, perform a fingertip test to confirm your result. If the fingertip test result still does not match how you feel, call your Healthcare Professional.

Lancing and Sampling from an Alternate Site

Sampling from your palm or forearm allows you to use your fingertips less often. You may find that obtaining a blood sample from an alternative site is less painful than using a fingertip. Getting a blood sample from your forearm or palm is different than getting a sample from your fingertips.

- **Forearm sampling:** Choose a fleshy area of the forearm away from the bone, visible veins and hair. Sometimes there is less blood flow to the forearm than to the fingertips. To help you get a large enough drop of blood, you may gently massage or apply warmth to the site to increase blood flow.
- **Palm sampling:** Choose a fleshy area on the palm below your thumb or little finger. Select an area away from veins or deep creases which may cause your blood sample to smear.



Forearm



Palm



The Lancing Device Clear Cap is used for forearm and palm sampling only. Replace the lancing device cap to the clear cap and follow the same steps as described in the chapter titled "Performing Blood Glucose Test".

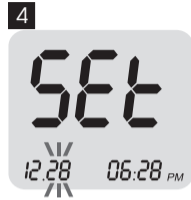
NOTICE:

- You may need to wait a little longer to get a large enough drop of blood from the forearm or palm. Do not squeeze the site excessively.
- If the sample drop of blood runs or spreads due to contact with hair or a crease in your palm, do not use that sample. Try puncturing again in a smoother area.
- You may have to adjust the lancing device to a deeper setting to get a large enough drop of blood.

Setting up Your Meter



1. Press and hold the 'M' button for roughly three seconds, you will hear a beep sound and the LCD Screen will display the screen icons of the meter.
2. Continue to hold the 'M' button and "SET" will appear on the screen.



3. Setting the Month : When the month blinks, press and release the 'C' Button until the correct month appears, then press the 'M' Button to set the correct month and move to the date setting.
4. Setting the Date : When the date blinks, press and release the 'C' Button until the correct date appears, then press the 'M' Button to set the correct date and move to the time setting.
5. Setting the Time Format : The meter can be set to show the time in AM/PM 12 hour format or 24 hour "Military Time". With the "12 h" blinking press the 'C' Button to move between 12 h and 24 h, then press the 'M' Button to set and move to the hour setting.

6. Setting the Hour : When the hour blinks, press and release the 'C' Button until the correct hour appears, then press the 'M' Button to set the correct hour and move to the minute setting.
7. Setting the Minute: When the minute blinks, press and release the 'C' Button until the correct minute appears, then press the 'M' Button to set the correct minute and move to the year setting.
8. Setting the Year: The year will appear on the screen, press and release the 'C' Button until the correct year appears, then press the 'M' Button to set the correct year and move to confirming the unit type mode.



9. Measurement Unit : The glucose measurement unit is defaulted to "mg/dL". Press the 'M' Button to move on to turning the "Beep" sound on or off.

NOTICE: This cannot be changed, if you have any questions concerning the Unit Type contact Customer Service at 1-888-885-6677.

CAUTION:

- Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and incorrect treatment.
- Contact your Healthcare Professional if you have any question about measuring units. This meter is preset to mg/dL. mg/dL is the unit of measure used in the U.S.



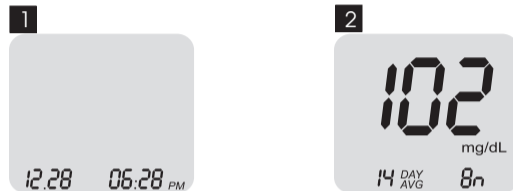
10. Turning the Beep Sound On or Off: The meter is preset to the beep sound "ON". To turn the beep sound off on the meter press the 'C' Button until "OFF" appears on the screen, then press the 'M' Button to confirm and move to Deleting Your Test Results.

NOTICE: Turning the Beep sound On or Off does not affect your glucose measurement.

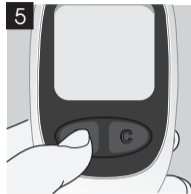


11. Deleting Your Test Result: Select the 'C' Button to toggle between "YES" and "NO". If you want to keep your readings in the memory toggle to "NO" then select the 'M' Button to confirm.
12. If you want to delete all of the readings in the memory toggle to "YES" then select the 'M' Button to confirm.
13. After deleting, the screen will show as pictured above. Press the 'M' Button again and the meter will turn off.

Reviewing Test Results



1. Begin with the meter off. Press the 'M' Button, you will hear a beep sound and the meter will turn on.
2. The screen will display the date and time. After 2 seconds, the last 14 days average result will be displayed with a sign "14 DAY AVG" and the number of test results for 14 days on the display. For example, "8n" above the picture means that there are eight (8) test results saved on the memory during the last 14 days.



3. Press the 'C' Button once and the screen will show the most recent test result.
4. Each time you continue to press the 'C' Button the screen will show the previous test result.
5. After you are done reviewing your test results, press the 'M' Button to turn off the meter.

NOTICE:

The meter has an automatic shut off and will turn off in roughly two (2) minutes if no changes are detected.

Downloading Test Results to PC

You can transfer test results from the Medisign MM1100 BT Blood Glucose Meter to a computer where they can be summarized in a report with graphs and tables. To use this feature you will need to download the Medisign Link Software and use the Medisign Link USB Cable.

For more information, please contact Customer Service at 1-888-885-6677, or visit our website at www.empecs.com

Pairing your Meter

Before Pairing Your Meter

Pairing must be completed between the Medisign MM1100 BT meter and your Bluetooth mobile device before your meter can communicate with your mobile device. Both devices must be within Ten (10) meter of each other in order to sync properly. Multiple meters can be connected to your mobile device; however, one meter cannot connect to multiple mobile devices at the same time.

Medisign MM1100 BT meter is compatible with:

- Android App OS version 4.3 or higher.
- Mobile devices compatible with Bluetooth 4.0

How to Pair Your Meter



1. Press the 'M' button to turn on Bluetooth.
2. If your mobile device is set to search other devices, you can find the Medisign MM1100 BT meter name along with the serial number displayed.
3. Select or Tap the name of the meter displayed you wish to connect.



4. If the mobile device and 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".

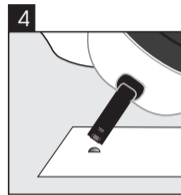
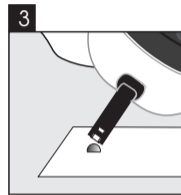
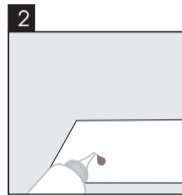
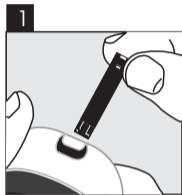
Control Test

Performing a Control Test

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

- You open a new box of test strips.
- You left the test strip container open.
- You want to check the meter and test strips.
- Your test strips were stored in extreme temperature or humidity.
- You dropped the meter.
- Your test result does not agree with how you feel.
- You want to check if you are testing correctly.

Performing a Control Solution Test



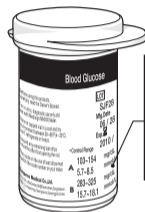
1. Insert the test strip with the black side and three(3) black lines facing up and pointing towards the test strip port. The code number will appear on the screen, verify that the code number displayed matches with the code number on the vial of test strips. If the two code numbers do not match, call Customer Service at 1-888-885-6677.
2. Shake well before using. Discard the first drop and wipe the dispenser tip. Squeeze a drop of control solution onto a clean, dry, non-absorbent surface. Do not apply control solution to the test strip directly from the vial. Replace the lid on the control solution vial immediately after use.

3. Gently touch the drop of the control solution to the tip of the test strip.
4. When the test strip confirmation window is full, the meter will beep. The meter will count down from five seconds and then show the reading. Make sure the reading on the screen is between the ranges displayed on your test strip vial (refer to page 44 for the control solution ranges).
5. Mark all control solution test with 'Control Solution Mark' to distinguish them from blood glucose test results in the meter memory. Marked control solution result will not be included in 14 day average. For more detailed information of Flagging Your Test Results refer to page 22 for help.

CAUTION:

- If you continue to get control solution results that fall outside of the range printed on the vial, the system may not be working properly. Do not use the meter. Please contact Customer Service at 1-888-885-6677.
- User should periodically compare the test system to another test system known to be well maintained and monitored by a healthcare provider.
- Use Medisign Glucose Control Solution for the Medisign MM1100 and Medisign MM1100 BT System Control Test.

Understanding Control Solution Test Results



Range (mg/dL)

Level 2(Normal): 64-96
Level 3(High): 213-288

The Range displayed is for EXAMPLE PURPOSES ONLY.

- The example label shown above on the test strip vial shows the acceptable ranges for Levels 2(Normal), 3(High) Control Solution for the Medisign MM1100 and Medisign MM1100 BT Glucose Meter.
- The result you get should be inside this range. Make sure you compare the result to the correct level of control.
- Each batch of test strips has different acceptable ranges.

Cleaning and Disinfecting

The meter should be cleaned and disinfected to prevent the transmission of blood-borne pathogens. Cleaning is done to remove germs, dirt and impurities from your Glucose Meter. Disinfection is done to kill the germs on the surface of your Glucose Meter.

Prepare a EPA-registered disinfectant, CaviWipes to clean and disinfect the outside of the meter. The towelette is available for purchase through Medex Supply Company, you can call them at 1-888-433-2300 or visit their website at www.medexsupply.com. This product can also be found through large online retail distribution sites such as www.amazon.com, www.ebay.com, etc.

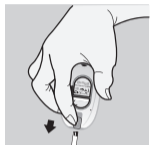
Cleaning Instructions : Use the CaviWipes Towelettes for a cleaner and disinfectant. Whenever your Glucose Meter is dirty, clean the outside of the meter with a new CaviWipes Towelette.

CAUTION:

Do not use other cleaners or disinfectants as they may damage the meter.

Disinfection Instructions: Your Glucose Meter should be disinfected once per week or as needed, and be cleaned prior to disinfecting. Use a second towelette to thoroughly wipe the entire pre-cleaned Glucose Meter and allow it to remain wet for two (2) minutes at 68°F per manufacture instructions. Allow to air dry when done.

STEP1



STEP2



STEP3



STEP4



STEP1: Dispose of the used test strip.

STEP2: Remove the wipe from the container and follow the instructions on the package. If needed wring the wipe slightly to remove excess liquid.

STEP3: Completely wipe the Glucose Meter including the front, back and sides, and take care not to get any liquid in the test strip, test strip port and serial port. Do not wrap the meter in a wipe. Take extreme care not to get liquid in the test strip, test strip port and serial port of the meter. Allow to remain wet for two (2) minutes at 68°F.

STEP4: Let the meter dry per the towelette manufacturer's instructions. Dispose of the wipe when finished.

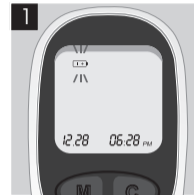
- User should wash their hands thoroughly with soap and water after handling the meter, or test strips.
- The life of the device is three (3) years. The Medisign MM1100 BT meter was demonstrated that there was no change in performance or in the external materials of the meter after 11,000 cleanings with disinfection cycles designed to simulate three (3) years for ten (10) times per day.

- For more information on cleaning and disinfecting, contact Customer Service at (1-888-885-6677).

CAUTION:

- Squeeze the excess liquid from the cloth before you wipe the meter's surface.
- The meter must be off when you clean or disinfect the meter.
- Do not get moisture on the test strip or in the test strip port or serial port.
- Do not spray any cleaning solution directly onto the meter.
- Do not put the meter under water or liquid.
- Immersing the meter in liquid will cause damage.

Replacing the Batteries





1. When the batteries are low the screen will display and blink the low battery icon in the top left hand corner. This indicates that there is only enough power left in the meter for about fifty more tests and the batteries should be replaced. When replacing the batteries your test results will be stored in the meter, however you may need to reset the date and time. Refer to pages 28-31 for more information.



- Open the battery compartment lid on the back of the meter and remove the batteries and replace them with two new CR2032 batteries. Make sure to align the + side facing up toward you. Once the new batteries are in place, snap the battery lid back onto the meter.

Screen Messages

Messages	Descriptions	Solutions
 <p>Er 1 12.28 06:28 PM</p>	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.
 <p>Er 2 12.28 06:28 PM</p>	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 appears on the screen.

Messages**Descriptions****Solutions**

The temperature is above or below the proper range for testing.

The temperature should be 50-104°F. Move the meter and test strips to an area that is within the temperature range to perform the test. Wait about twenty minutes or until the meter has reached the proper range and retest. Do not raise or lower the meter temperature artificially.

Messages**Descriptions****Solutions**

There is not enough blood in the strip to perform a test.

Repeat the test with a new test strip and make sure enough blood has been applied to the strip.



The wrong strip has been put into the meter.

Make sure you are using an Medisign MM1 100 test strip and repeat the test.



There is an internal error with the meter.

Please contact Customer Service at 1-888-885-6677.

Messages

Descriptions

Solutions



When the test result is higher than 600mg/dL, the screen will show the "Hi" mark. This indicates that the value of your blood glucose is too high.

Retest with a new test strip. If the "Hi" mark appears again, please call your doctor or Healthcare Professional immediately.



When the test result is lower than 20mg/dL, the screen will show the "Lo" mark. This indicates that the value of your blood glucose is too low.

Retest with a new test strip. If the "Lo" mark appears again, please call your doctor or Healthcare Professional immediately.

Troubleshooting

Causes

Solutions

The meter does not work after the blood is applied.

- Make sure that the test strip is inserted into the test strip port 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. Also make sure the test strip has not been out of its container for any extended period of time.
- Make sure the test strip has not been used before.
- Verify the expiration date on the test strip vial.

Causes	Solutions
	<ul style="list-style-type: none"> • Make sure the test strip vial has not been opened for longer than three (3) months. • Make sure the meter code and test strip code match.
The thermometer icon (🌡️) appears on the screen.	<ul style="list-style-type: none"> • Place the meter and test strip in a temperature environment of 50-104°F. You should use it after about 20 minutes in the appropriate conditions. • If the thermometer icon is constantly showing, contact Customer Service at 1-888-885-6677.
The meter does not work after the test strip is inserted.	<ul style="list-style-type: none"> • Make sure the test strip is completely inserted into the test strip port. • Make sure the batteries are inserted correctly, with the + sign up and facing the right direction.

Specifications

Product Name	Medisign MM1100 BT Blood Glucose Monitoring System
Test Sample	Fresh capillary whole blood
Calibration	Plasma-equivalent
Sample size	0.5µl
Test Strip Type	Medisign MM1100 Blood Glucose Test Strip
Measuring Range	20 - 600 mg/dL
Measuring Time	5 Seconds
Power	(2) 3.0 Volt CR2032 lithium batteries
Battery Life	Approximately 1000 tests
Memory Capacity	300 test results
Data Transport	Wireless (Bluetooth 4.0), USB Data Transfer Cable

Display	LCD
Operating Temp	50 - 104°F
Operating Humidity	10 - 90 % RH
Storage Temp	39 - 86°F
Dimensions	18 x 51 x 88 mm
Weight	48g (with batteries)
Wireless Frequency	2.4 GHz Band

Warranty

Tianjin Empecs Medical Device guarantees that the Medisign MM1100 BT Blood Glucose Meter shall be free of defects in material and workmanship for a period of three years. This guarantee is valid from the date of purchase. This guarantee extends only to the original purchaser and is not transferable.

The warranty ceases to apply under the following conditions:

- The meter is damaged as a result of incorrect use.
- The meter is damaged as a result of natural disasters (e.g. hurricane, earthquake etc.).
- The meter is damaged due to using incompatible products.
- The meter is damaged as a result of attempting repair.

Disposing of your Meter

During blood glucose measurement the meter itself may come into contact with blood. Used meters therefore carry a risk of infection. Please dispose of your used meter - after removing the batteries - according to the regulations applicable in your area. For information about correct disposal, please contact your local council and authority. The meter falls outside the scope of European Directive 2002/96/EC (Directive on waste electrical and electronic equipment (WEEE)).

Blood Glucose Target Range

Normal blood glucose reference value for non-diabetics is as follows:

- Before eating : < 100 mg/dL
- 2 hours after meals : <140 mg/dL

In case results are out of reference range, please contact your Healthcare Professional and follow their advice.

Reference: American Diabetes Association, Clinical Practice Recommendations (2013) Diabetes Care, Vol. **36**, Supplement **1**, p S1 - S100

Additional Supplies Available

The following supplies and accessories are available from your supplier, for more information contact Customer Service at 1-888-885-6677.

Medisign Link Cable

Medisign Link Software

Medisign MM1100 Test Strips

Medisign Glucose Control Solution

FCC Part 15.19

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.

FCC Part 15.21

Any changes or modifications (including the antennas) to this device that are not expressly approved by the manufacturer may void the user's authority to operate the equipment.

RF Exposure Statement (2.1093)

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

This device and its antenna must not be co-located or operating in conjunction with any other antenna or transmitter.

This equipment should be installed and operated with a minimum distance of 5mm between the radiator and your body.

FCC Part 15.105 (B)

Note : 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 or more 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 connected.
- Consult the dealer or an experienced radio/TV technician for help.

Modifications not expressly approved by the manufacturer could void the user authority to the operated equipment under FCC rules.