MIO

MIO Blood Glucose Monitoring System

# USER MANUAL

# Blood Glucose Monitoring System

Dear MIO System User,

Thank you for choosing the MIO Blood Glucose Monitoring System! MIO Blood Glucose Monitoring System is designed for easy test of blood glucose and helps you keep blood glucose under control.
Read this User Manual carefully before you use your meter system. This manual will help you to get comfortable using the MIO Blood Glucose Monitoring System and get reliable test results. Please keep your User Manual in a safe place, you may want to refer it in the future.

Thank you again for choosing the MIO System.

## Intended Use

MIO Blood Glucose Monitoring System is comprised of the MIO Blood Glucose Meter and the MIO Blood Glucose Test Strips. MIO Blood Glucose Monitoring System is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended for self-testing outside the body (in vitro diagnostic use), and should only be used by a single person and should not be shared.

## Principle of Operation

MIO Blood Glucose Monitoring System is designed to quantitatively measure the glucose concentration in fresh capillary whole blood. The glucose measurement is achieved by using the amperometric detection method. The test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is pulled into the tip of the test strip through capillary action. Glucose in the sample reacts with glucose oxidase and the mediator. Electrons are generated, producing a current that is positive correlation to the glucose concentration in the sample. After the reaction time, the glucose concentration in the sample is displayed .

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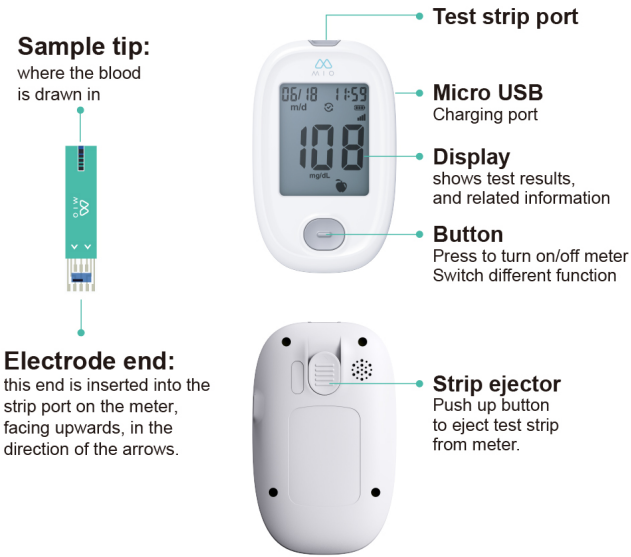
# CHAPTER 1: UNDERSTANDING YOUR TESTING TOOLS

## Your System Overview



MIO Lancets

MIO Lancing Device

MIO Control Solution

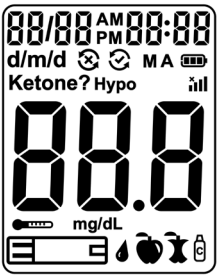
Note:
The MIO Blood Glucose Test Strips, MIO Control Solution, MIO Lancing Device and MIO Lancets are not included in the meter box but are necessary for use, please contact 24/7 MIO Customer Support at (833)445-5666 for purchase.

## Your Meter Display

The picture below shows all the symbols that appear on your meter display.

Please make sure the display is working properly before testing. When the meter is off, press and hold ◎ to see the complete display. All display segments will appear. If you need more time to check the display, repeat the above operation.

All display segments should be clear and exactly like the picture below. If not, contact 24/7 MIO Customer Support at (833)445-5666 for help.




| Icon | What It Means |
|---|---|
| 88/88 | The top left area on the screen indicates date. |
| 88:88 | The top right area on the screen indicates year or time. |
| AM PM | The top middle area on the screen indicates morning or afternoon time. |
| d/m/d | Indicates the display form of day and month (d/m) or month and day (m/d). |
| | Data transmitted successfully. |
| | Data not transmitted. |
| M | Indicates test result history. |
| A | Indicates average value. |
| | Indicates the battery level. |
| Ketone? | It recommends performing a ketone measurement based on the high glucose test result (⩾300mg/dL) obtained from this meter. |

| | |
|---|---|
| **Hypo** | Indicates that a low glucose test result may cause hypoglycemia. |
| | Signal strength. |
| 88.8 | Center area on the display that shows test results or error codes. |
| | Indicates the temperature is not suitable for testing. |
| **mg/dL** | Test results are displayed as mg/dL. |
| | When strip is inserted, the drop will flash, indicating the system is ready to test. |
| | Pre-meal marker. |
| | Post-meal marker. |
| C | Control test result. |

***Notes:***

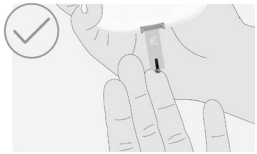
*Your MIO Meter is preset with beep sound function, the meter will beep when:*

- *Turn on the meter.*
- *When setting the date and time (in set-up mode).*
- *When the test strip is inserted and ready for application of blood or control solution.*
- *When sufficient blood or control solution is pulled into the test strip.*
- *When the test is complete.*
- *If any error occurs during operation.*

**Meter Use and Precautions**

- The meter is indoor use.
- The meter display blood glucose concentration in milligrams per deciliter (mg/dL) only.
- Meter will shut off by itself after 2 minutes of inactivity.
- Keep the strip port area clean.
- Keep your meter in hen temperature range 41-113° F and relative humidity range 10-90%.Do not leave it in your car.
- Do not drop the meter or get it wet. If you do drop the meter or get it wet, check the meter by running a quality control test. Refer to **Testing with Control Solution** for instructions.
- Do not use the meter if it drops into water or other liquids or splashing water on to it.
- If the system is used in a manner not specified by the manufacturer, the protection provided by the system can be impaired.
- Do not transfer the test strips to a new vial or any other container.
- Do not drop the blood on the test strip. The blood is pulled into the tip of the test

strip through capillary action:



Check the expiration dates and discard dates on your test strips vial label and control solution vial label.
Use only MIO Blood Glucose Test Strip with your MIO Blood Glucose Meter.
Use only MIO Control Solution with your MIO Blood Glucose Meter and MIO Blood Glucose Test Strip.
Keep the meter and all associated parts out of reach of children.
Wash and dry your hands well before and after testing.

## Important Safety Information

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection. Please follow proper precautions when handling your meter and lancing device.
- For more information, please refer to the FDA Public Health Notification: “Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010) at: https://wayback.archive-it.org/7993/20170111013014/http:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
  You may also refer to the “CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010) at http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html
- Please contact your physician or diabetes healthcare professional if you determine to make a change on your current medical therapy or diet activity based on test results.
- Refer to the Cleaning and Disinfection section for details on cleaning and disinfecting the meter.
- Follow proper precautions and all local regulations when disposing of the meter.

**Limitations**

- It may cause inaccurate result if hematocrit level is outside the range (20%~70%). Talk to your healthcare professional to find out your hematocrit level.
- Not for use on critically ill patients.
- Not for use on patients who have been diagnosed by a healthcare provider with a dehydration disease requiring hospitalization.
- Not for use on patients who have been diagnosed by a healthcare provider with a hypotensive disease requiring hospitalization;
- Do not test your blood glucose during or soon after a xylose absorpition test. Xylose in the blood can give inaccurate results with this meter.
- Not for neonatal use.
- Not for screening for or diagnosis of diabetes mellitus.
- Do not use the system above 10,413 ft (3,174 meters) in altitude.
- This meter is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this meter on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

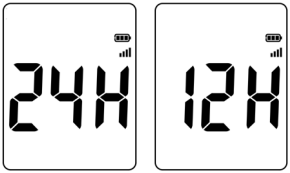
# CHAPTER 2: SETTING UP YOUR SYSTEM

Before using your meter for the first time, make sure to set up your meter properly.

## Set the Date and Time

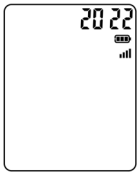
### 1. Enter the setting mode and set the clock

When the meter is off, press and hold ◎ until the meter beeps to enter the set up mode. Then set the clock for either 24 or 12 hour mode. Press ◎ to adjust it then press and hold ◎ to save your choice. Start setting the year, month and day.

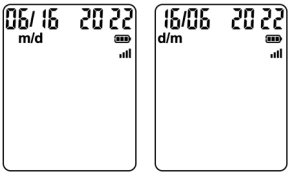



### 2. Set the date

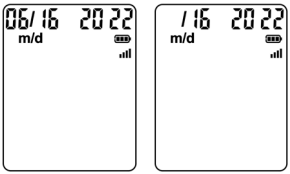
The year will now flash. Press ◎ to adjust it, then press and hold ◎ until the meter beeps to set, then it will shift to the next digit for setting. Repeat the above action until the year setting is completed.



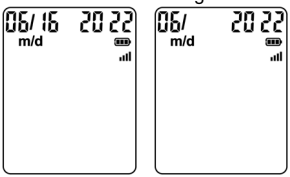

The display form of day and month will now flash, press ◎ to set the display form to m/d or d/m mode, press and hold ◎ until the meter beeps to set.
The meter will prompt you to set the month.




The month will now flash, press ◎ to adjust the month, press and hold ◎ until the meter beeps to set.

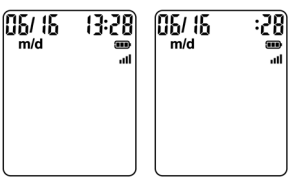



The day will now flash. Press ◎ to adjust the day, press and hold ◎ until the meter beeps to set, then it will shift to the next digit for setting.

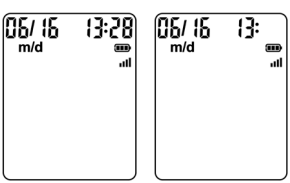



**3. Set the time**

After the date setting is completed. Press ◎ to adjust the current hour, press and hold ◎ until the meter beeps to set, then it will shift to the next digit for setting.




The minute will now flash. Press ◎ to adjust the minute, press and hold ◎ to set.

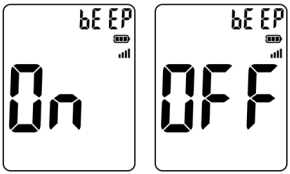



***Note:***

*Before your first use of the meter for testing, please adjust the meter settings to set the correct date and time, ensuring that results stored in the memory are shown with the correct date and time.*

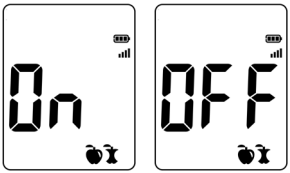
## Set the Audio Feature

After you set the time, press ◎ to select “On” or “OFF”. Press and hold ◎ to set.



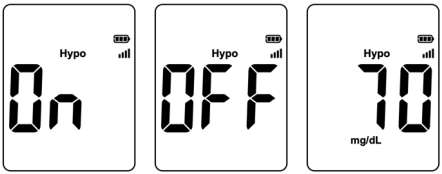

## Set the Meal Marker

After setting the audio feature, the symbols of will now flash, along with the word “On” or “OFF” on the display. Press ◎ to adjust to turn the meal marker function on or off, press and hold ◎ to set.




## Set the Hypoglycemia (Hypo) Warning

After you have confirmed the meal marker setting, the **Hypo** flashes on the display along with “On” or “OFF” on the display. Press ◎ button to turn the Hypo alarm function on or off, then press and hold ◎ button to set. If you select the Hypo alarm to be “On”, the display shows 70 mg/dL. as default Press ◎ button once to adjust blood glucose level (the level increases by 1 mg/dL). You can adjust the range from 60 to 80 mg/dL. Press and hold ◎ button to confirm.



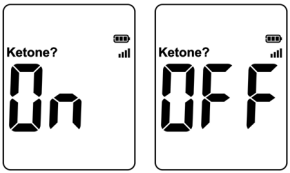
***Notes:***

- Hypo Alam (warning) is a reminder displayed on meter for user that the measured glucose level is equal or less than a settable glucose value that has been recommended by your healthcare professional.
- You can set the Hypo Alarm to let you know when your blood glucose is possibly too low. If you select the Hypo Alarm to be “On”, the “Hypo” warning will appear when your blood glucose test result is below your setting blood glucose level. Please talk ti your healthcare professional ti help you decide and set the blood glucose level that suits your physical condition.

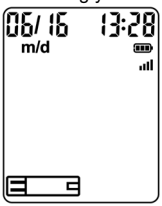
## Set the Ketone Warning

The icon is to provide a ’high glucose’ alarm that recommends performing a ketone measurement. However, the icon does not mean this meter measures ketones.

After the hypo warning setting is completed, the **Ketone?** symbol will now flash, along with word “On” or “OFF” on the display. Press button to turn the Ketone Warning on or off; press and hold to set.




Now you have completed your meter set up. Power button for 5 seconds when a symbol of a flashing strip appears letting you know the meter is ready to test.




Once all the settings are completed, if you want to change the setting, please press and hold the power button for 5 seconds when the meter is powered off and then to return to the set-up mode.

# CHAPTER 3: PERFORMING A TEST

Set up your meter correctly and have all the materials you will need ready before you begin testing. This includes your MIO Blood Glucose Meter, MIO Blood Glucose Test Strips, and MIO lancing device and lancets.

## Preparing the Test Strip

1. Wash and dry your hands well before testing.
2. Remove a test strip from the test strip vial. Tightly close the vial cap immediately after you have removed the test strip.
3. Insert the test strip into the meter in the direction of the arrows. Meter turns on after a beep.

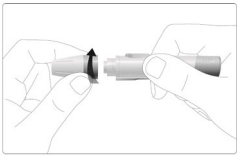
4. A symbol with a flashing blood drop will appear letting you know the meter is ready to test.

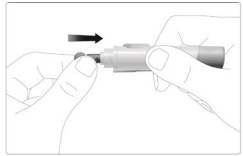
***Note:***
*Check the expiration and discard dates on the test strip vial. All expiration dates are printed in Year-Month-Day format. 2023-01-01 indicates 1st, January, 2023. Your MIO test strips have 6 months shelf life after you first open the test strip vial. Write the discard date on the vial label when you first open it. Make sure the test strip does not appear damaged. Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water to wash hands to increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no cream or lotion on the test site.*

## Preparing the Lancing Device

For fingertip sampling, adjust the depth penetration to reduce the discomfort. You do not need the clear cap for fingertip sampling.

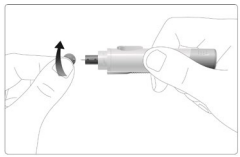
1. Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancing device and push it until the lancet comes to a complete stop in the lancing device.



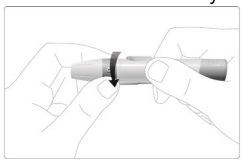


***Note:*** *The **MIO** lancing device uses **ONLY MIO** sterile lancets.*

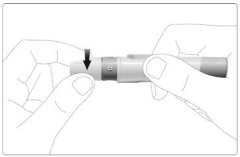
2. Hold the lancet firmly in the lancing device and twist the safety tab of the lancet until it loosens, then pull the safety tab off the lancet. Save the safety tab for disposing the used lancet.

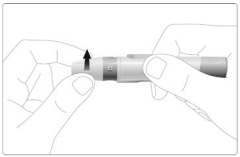


3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed lancet. Make sure the cover is fully sealed on the lancing device.



4. Adjust the puncture depth by rotating the lancing device cover. There are 5 puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.





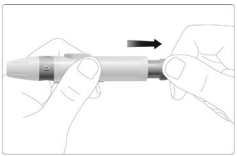
Adjustment:

1 for delicate skin
2 and 3 for normal skin
4 and 5 for calloused or thick skin

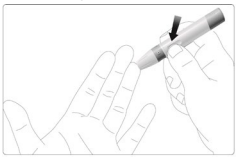
***Note:*** *Greater pressure of the lancing device against the puncture site will also increase the puncture depth.*

## Getting a Blood Drop for Testing

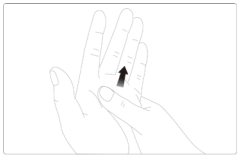
1. Pull the cocking barrel back to set the lancing device. You may hear a click to indicate the lancing device is now loaded and ready for obtaining a drop of blood.

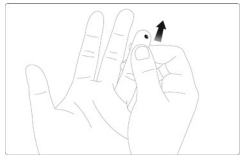


2. Press the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You should hear a click as the lancing device activates.

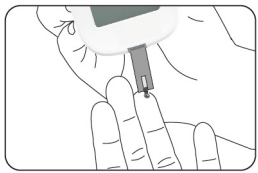


3. Remove the first drop of blood with a clean paper towel to ensure a more accurate result. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume (half the size of a match head). Avoid smearing the drop of blood. For the greatest reduction in pain, lance on the side of the fingertip. Test immediately after a good blood drop has formed.



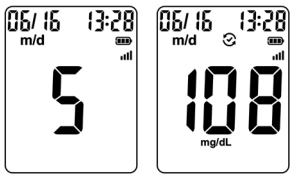


4. Immediately touch the tip of the test strip to the drop of blood. The blood will be pulled into the test strip through the tip. Make sure that the blood sample has fully filled the check window of the tip of the strip. Hold the tip of the test strip in the blood drop until the meter beeps.



***Note:***
*If the blood sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.*

5. The meter counts down 5 seconds and your result appears on the display after a beep. The test result will automatically be stored in the meter memory. Please do not touch the test strip during the countdown as this may result in an error.

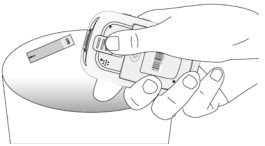



6. After the testing is completed, the measurement data will be transmitted.

***Note:***
*You could log in to the MIOCONNECT Web App to view the historical measurement data from the website: play.mio-labs.com*

**Discarding the Used Test Strip**

You can eject and discard the used test strip by using the strip ejector.

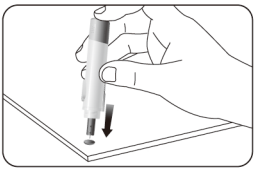


**Potential Biohazard**

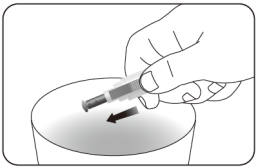
Dispose of the used test strips as medical waste.

## Removing the Used Lancet

Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface and carefully insert the lancet needle into the safety tab.



Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to release the used or contaminates lancet in an appropriate container with a potential biohazard identification. Do not use your fingers to pull the used lancet out to prevent injury from the lancet. Dispose of used lancets and follow local regulations for proper disposal to prevent injury from the lancets.



Place the lancing device cover back on the lancing device.

Please wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

**Potential Biohazard**

Always dispose of the used or contaminated lancet properly toprevent potential injury or infections to others.

**Caution:**

- *Lancing device is intended only for a single user and should not be shared.*
- *Check and do not use the lancet safety tab is missing ro loose when you take the lancet out from the package.*
- *Do not use the contaminated or aropped lancet that safely tab has been removed*
- *Be cautious whenever the lancet needle is exposed.*
- *Do not reuse lancet, and do not share lancet with anyone including family members.*

**Expected Diabetes Control Goal:**

| Time | Normal plasma glucose range for adults without diabetes, mg/dL |
|---|---|
| Before breakfast (fasting) | <100 |
| 2 hours after a meal | <140 |

Reference: American Diabetes Association;Standards of Care in Diabetes—2023 Abridged for Primary Care Providers.Clin Diabetes 2 January 2023; 41 (1): 4–31.

Note: Please work with your healthcare professional to determine a target range that works best for you.

## Questionable or Inconsistent Results:

### Symptoms of High or Low Blood Glucose:

You can better understand your test results by being aware of the symptoms of high or low blood glucose. According to the American Diabetes Association, some of the most common symptoms are:

**Low blood glucose (Hypoglycemia):**

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- irritability
- seizure
- extreme hunger
- dizziness

**High blood glucose (Hyperglycemia):**

- frequent urination
- excessive thirst
- blurred vision
- increased fatigue
- hunger

**Ketones (ketoacidosis):**

- shortness of breath
- nausea or vomiting
- very dry mouth

### If your blood glucose result does not match how you feel, please*:*

- Check the expiration date and the discard date of the test strip. Make sure that the test strip vial has not been opened for more than 6 months.
- Confirm the temperature in which you are testing is between 41-113°F.
- Make sure that the test strip vial has been tightly capped.
- Make sure the test strip has been stored at 36-86°F, 10-90% humidity.
- Make sure the test strip was used immediately after removing from the test strip vial.
- Make sure that you followed the test procedure correctly.
- Perform a control solution test (See **Testing with Control Solution** for instructions).
- After checking all the conditions listed above, repeat the test with a new test strip. Please contact 24/7 MIO Customer Support at (833)445-5666 for technical support or questions.

As glucose levels range for self-monitoring may vary from person to person, please check with your healthcare professional to determine the levels range you need to monitor.

*•Please contact your healthcare professional if your test result is below the lower limit of your level range or you see LO (less than 20 mg/dL).*

*•Please contact your healthcare professional If you test result is above the upper limit of your level range or you see HI (greater than 600 mg/dL).*

*•Please contact your healthcare provider if you obtain results that are not consistent with the way you feel, and to not change your medication or food regimen without approval from a healthcare provider.*

**Precision and Accuracy**
**Linearity Results:**
Lot 1: y = ; $R^2$=
Lot 2: y = ; $R^2$=
Lot 3: y = ; $R^2$=

The results support the claimed measurement range of 20-600 mg/dL.

**Within-Run Precision:**

| Within-Run Precision- Blood | | | |
|---|---|---|---|
| Interval | Glucose Concentration | Standard Deviation (SD) or Coefficient of Variation (CV) | SD 95% CI or CV 95% CI |
| 1 | 39.8 mg/dL | 1.8 mg/dL | [1.2mg/dL, 2.4mg/dL] |
| 2 | 70.5 mg/dL | 2.3 mg/dL | [1.3mg/dL, 2.9mg/dL] |
| 3 | 127.9 mg/dL | 2.8% | [1.5%, 3.9%] |
| 4 | 199.0 mg/dL | 3.0% | [1.6%, 3.6%] |
| 5 | 349.6 mg/dL | 2.9% | [1.5%, 3.9%] |

**Intermediate Precision:**

| Intermediate Precision-Control Solution | | | |
|---|---|---|---|
| Interval | Glucose Concentration | Standard Deviation (SD) or Coefficient of Variation (CV) | SD 95% CI or CV 95% CI |
| 1 | 40.0 mg/dL | 1.8 mg/dL | [1.0mg/dL, 2.6mg/dL] |
| 2 | 70.1 mg/dL | 2.0 mg/dL | [0.9mg/dL, 3.0mg/dL] |
| 3 | 129.8 mg/dL | 2.4% | [1.0%, 3.5%] |
| 4 | 199.5 mg/dL | 2.3% | [1.2%, 3.2%] |
| 5 | 349.9 mg/dL | 2.3% | [1.4%, 3.1%] |

**User Evaluation:**
352 samples were tested using three MIO Blood Glucose Test Strips lots. The results were compared to the YSI Model 2300 Analyzer.

**Table 1- Linear Regression Results**

| | |
|---|---|
| Slope | mg/dL |
| Intercept | |
| Correlation coefficient (R) | |
| Number of sample | |
| Range tested | to mg/dL |

**Table 2-Consumers Accuracy Results**

Accuracy for Home Use by Lay-Users
MIO Blood Glucose Meter result may vary slightly from your actual blood glucose value. This may be due to slight differences in technique and the natural variation in the test technology.
The chart below shows the results of a study where 352 typical users used the MIO Blood Glucose Meter to test their blood glucose level. In this study, MIO Blood Glucose Meter gave results within 15% of their true blood glucose level 352 out of 352 times.

| Difference range between the true blood glucose level and MIO Blood Glucose Meter result | Within 5 % | Within 10 % | Within 15 % | Within 20 % |
|---|---|---|---|---|
| The percent (and number) of meter results that match true blood glucose level within x% | XX% ( / ) | | | |

## Comparing Meter and Laboratory Results

**Before you go to the lab**:

- ➢ Perform a quality control test to make sure the meter is working properly.
- ➢ If possible, fast for at least eight hours before testing,
- ➢ Bring your meter and test strips.

**While you stay at the lab:**

- ➢ Wash your hands before obtaining a blood sample.
- ➢ Obtain and test the blood samples immediately for your tests.
- ➢ Follow User Manual for performing a blood glucose test.

***Note:***

Users should periodically review their technique and compare a result obtained with their meter to a result obtained using a laboratory method or a well-maintained and monitored system used by your healthcare provider.

## Testing with Control Solution

### Why Perform Control Tests

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

- Once a week.
- When using or when opening a new vial of test strips.
- When you suspect that the meter and test strips are not working together properly.
- After cleaning and disinfecting your meter.
- You dropped the meter.
- Always perform a quality control test if you suspect your results are inaccurate or do not match how you are feeling.

### About the Control Solutions

- Only use MIO Control Solutions (1, 2 or 3) to practice on the system.
- Your meter automatically recognizes the control solution.
- The control solution results are not including in the average value calculation.
- Store the control solution at 36-86°F, 10-90% humidity.
- All expiration dates are printed in Year-Month-Day format. 2023-01-01 indicates 1st January, 2023.
- Do not use control solution that is out of the expiration date or discard date (the control solution will expire 6 months after the vial is opened for the first time).
- Shake the vial well before use.
- Close the vial tightly after use.

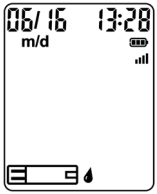
**Performing a Control Test**

1. Remove a test strip from the test strip vial. Tightly close the vial cap immediately after you have removed the test strip.

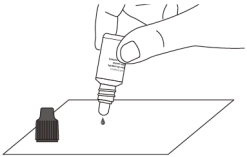
***Note:*** *Check the expiration and discard dates of the test strips. Do not use the expired test strip.*

2. Insert a test strip into the meter in the direction of the arrows.

3. The meter turns on after a beep. An image of a test strip with a flashing blood drop will appear letting you know the meter is ready to test.




4. Shake the control solution vial thoroughly. Squeeze the control solution vial gently and discard the first drop. Squeeze out a second small drop on a clean nonabsorbent surface.

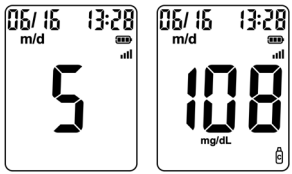


***Note:*** *Do not apply control solution to the test strip directly from the vial.*

5. Immediately touch the tip of the test strip to the drop of control solution. The control solution is pulled into the test strip through the strip tip.

***Note:*** *If the control solution sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.*

6. Hold it in the drop until the meter beeps, and then you see the meter count down on the screen, followed by your control test result.

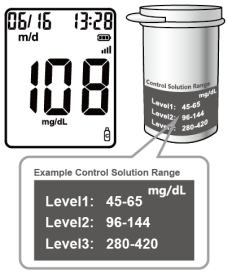



***Note:*** *The meter will automatically recognize and mark the control result for you. Control results are not included in the 7, 14 and 30 day average calculation.*

**7.** Please wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

## Understand Control Test Result

Compare your control test result with the ranges printed on the test strip vial label.




***Remark:*** *The ranges in the image above are only example and the ranges on the vial in use should be referenced.*

***Notes:***
*If your control test result is out of range:*

- *Check the expiration dates and discard dates of the test strip and control solution. Make sure that the test strip vial and the control solution vial have not been opened for more than 6 months. Discard any expired test strips or control solution.*
- *Confirm the temperature in which you are testing is between 50-104°F.*
- *Make sure that you stored strip and control solution at 36-86°F, 10-90% humidity.*
- *Make sure that the test strip vial and the control solution vial have been tightly capped.*
- *Make sure the test strip was used immediately after removing from the test strip vial.*
- *Make sure the control solution was mixed well.*
- *Confirm that you are using MIO brand control solution.*
- *Make sure that you followed the test procedure correctly.*

After checking all of the conditions listed above, repeat the control solution test with a new test strip. If your results still fall out of the range indicated on the test strip vial label, your meter or test strips may not be working properly. **DO NOT** use the system to test blood. Contact 24/7 MIO Customer Support at (833)445-5666. Please contact your healthcare professional if you need help.
To turn your meter off, just remove the test strip. Dispose of the used test strips as medical waste. The result will be automatically marked and stored in the meter memory. Control results will be not included in your blood glucose averages.

## Using the Meter Memory

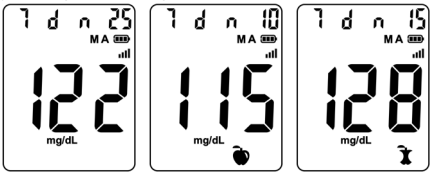
Your meter automatically stores up to 500 results with time, date and meal marker. Test results are stored from the newest to the oldest. The meter will also calculate the average values of blood Glucose records from the last 7, 14 and 30 days.
***Notes:***

- *If there are already 500 records in memory, the oldest record will be erased to make room for a new one.*
- *Control results of blood glucose are not included in the 7, 14 and 30 day average calculation.*

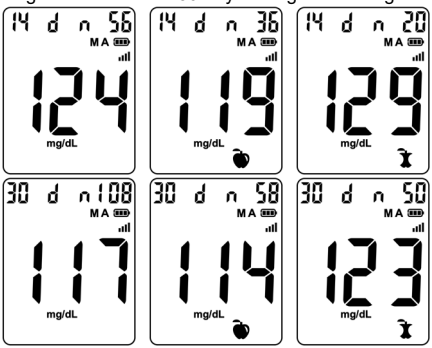
## Viewing Your Test Results

When your meter is off, press button to turn meter on. After a beep, a symbol of a test strip flashes on the display. Press button to review previous results in order. Results will be shown starting with the most recent. Each result will show the date and time the test was taken.

Continue press ◎ button for 2 seconds until the 7-day average of blood glucose appears in the center of the display. If you want to review the memory after you immediately performed a test, when the test result on the display, press ◎ button to see the 7-day average of blood glucose.




Continue to press ◎ button to view the 14-day average of blood glucose, then press ◎ button again to review the 30-day average of blood glucose.




When **END** appears on the display, you have viewed all of the results in the memory.

# CHARTER 4: MAINTENANCE AND TROUBLESHOOTING

Proper maintenance is recommended.

## Charging the Battery

When the meter needs to be charged, the Empty Battery Symbol ( ) will appear. When the Empty Battery Symbol ( ) and 'E11' appear on the screen, the meter cannot be used. You must charge the battery before using your meter.

*The meter battery may be charged using one of the following options:*

- *Micro USB cable (computer charging)*
- *Micro USB cable with the AC adapter (wall charging)*

*If you need the AC adapter which is not included in your kit, please contact your local distributor.*

**Caution:**

- Do Not charge the meter outdoors or in a wet area.
- Do Not use the Micro USB cable, AC adapter or meter if it is damaged, discolored, abnormally hot, or has an unusual odour. Contact your local distributor.
- Do Not plug the AC adapter into a wall socket and leave it unattended.
- Verify that the wall socket voltage matches the AC adapter voltage.
- Do Not allow unsupervised children to charge the meter battery.

**Caution:**

Do Not insert a test strip when the meter is connected to a computer or wall outlet.

***NOTE:***

- *Using the Micro USB cable or AC adapter charges the battery in about 3 hours.*
- *When using the USB port on your computer to charge the battery, be sure the computer is turned on and not in standby mode. If the meter does not charge, try using another USB port on your computer.*
- *To optimize battery life, it is best to charge the battery when the Empty Battery Symbol ( ) appears.*

**Caution:**

- *Contact seller to confirm whether the AC adapter meets following specifications before purchasing it:*
  - *Input: 100-240V~, 50/60Hz, 0.2A Max;*
  - *Output: 5.0V, 1.0A;*
  - *standard ANSI/AAMI ES 60601-1 or IEC 60601-1.*
- *If you use the USB port on your computer to charge the battery, please ensure the computer meets the standard IEC 60950.*

***Warning:***

*Please note that the battery is not removable. If the battery needs to be separated for sorting and discarding due to scrap of the product, please keep it away from children. A lithium battery is poisonous. If swallowed, immediately contact your doctor or poison control center. Discard battery according to your local environmental regulations.*

## Caring for Your Glucose Monitoring System

- Store meter in the carrying case provided whenever possible.
- Wash and dry hands well before handling to keep the meter and test strips free of water and other contaminants.
- MIO Blood Glucose Meter is a precision electronic instrument. Please handle it with care.
- Avoid exposing meter,test strips and control solution to excessive humidity, heat, cold, dust, or dirt. The operating conditions for meter and test strips are 41-113°F, relative humidity 10-90%. The operating conditions for control solution are 50-104°F, relative humidity 10-90%. Avoid heat and direct sunlight.

## Cleaning and Disinfection

The purpose of cleaning step is to remove the potential dirt and dust particles and make clean surface for the next disinfection step. The purpose of disinfection step is to disinfect the microorganism on whole surface of meter.

Use only Clorox™ Healthcare Bleach Germicidal Wipes, which has been proven to be safe to use with the MIO Blood Glucose Meter. Clorox™ Healthcare Bleach Germicidal Wipes are available by visiting and purchasing at http://www.walmart.com, http://www.staples.com/, and https://www.amazon.com/.

The meter should be cleaned and disinfected a minimum of once per week. The process has been validated for 608 cycles, which is equivalent cleaning and disinfecting your meter every 3 days for 5 years. This is to ensure that your meter will operate properly over the 5-year life of the meter.

*Warning: If the meter is being operated by a second person who is providing testing assistance to you, the meter should be cleaned and disinfected prior to use by the second person.*

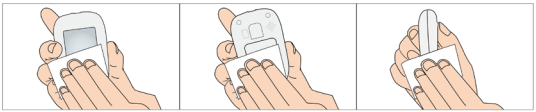
***Notes:***

- *Do not use alcohol or any other solvent that have not been proved to be safe and effective for use with the device.*
- *Do not allow liquid, dirt, dust, blood, or control solution to enter the test strip port or the USB port.*
- *Do not squeeze the wipe or gauze into test strip port.*
- *Do not spray cleaning solution on the meter.*
- *Do not immerse the meter in any liquid.*
- *Please refer to the safety instruction in the labeling of Clorox Healthcare Bleach Germicidal Wipes before using wipes.*

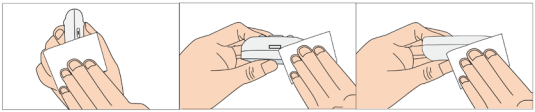
**Cleaning Your Meter**

Step 1: Take one piece of Clorox™ Healthcare Bleach Germicidal Wipes (EPA Registration No. 67619-12) from the container.

Step 2: Clean the entire surface of the meter including the front, back, left, right, top and bottom sides of the meter, and specifically also including the test strip port, test strip ejector, button, material seams and USB port for one minute. This cleaning is to prepare a clean meter surface for a disinfection process.



Front side Back side Right side

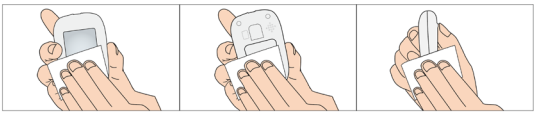


Left side Top side Bottom side

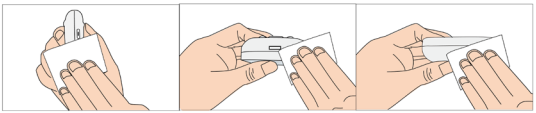
**Disinfecting Your Meter**

Step 1: After cleaning your meter, take out another new piece of Clorox™ Healthcare Bleach Germicidal Wipes.

Step 2: Wipe the entire surface of the meter, The parts of the meter that are particularly susceptible to blood contamination should be wiped, which include the test strip port, test strip ejector, button, material seams, USB port by a back and forth movement,



Front side Back side Right side



Left side Top side Bottom side

Step 3: Cover the meter with the wipe and keep the meter surface wet for at least one minute.
Step 4: Remove the wipe and wait for the surface of the meter to be dry.
Step 5: Please wash hands thoroughly with soap and water after completing the disinfection procedure.

***Notes:***
*Although it has not been observed, some alterations may appear on your meter due to the cleaning and disinfection procedure. Such as: cloudy display window, plastic housing cracking, meter's button does not function, partial display on full screen, unable to execute the meter's initial set up, etc. If you notice any of these external changes to your meter or any changes to the performance of your meter stop using the meter and please contact 24/7 MIO Customer Support at (833)445-5666 for help.*
If you have questions about cleaning or disinfection, contact 24/7 MIO Customer Support at (833)445-5666

## Troubleshooting Guide

| What You See | What It Means | What You Should Do |
|---|---|---|
| E 1 | Blood or control solution was applied to the test strip before the flashing blood drop appeared on the display | Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing. |
| E 2 | The meter is sensing a used or contaminated test strip. | Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing. |
| E 3 | Incorrect test strip. | Discard the test strip and repeat the test with a new test strip. Make sure that you are using a MIO test strip. |
| E 4 | Incorrect sample. | Discard the test strip and repeat the test with a new test strip. Make sure that only human capillary blood and MIO control solution are used for the test. |
| E 5 | Temperature out of range. | Move to an area that is within the operating range for the meter. Let the meter adjust to this temperature for 20 minutes before performing a test. |
| E 6 E 7 | Potential hardware error. | Restart the meter. If the problem continues, contact 24/7 MIO Customer Support at(833)445-5666. |
| E 8 | A test strip was inserted while the meter was connected to a computer or wall outlet. | When the charge is completed (about 3 hours for charging an empty battery), remove the Micro USB cable from the meter, and then take a test. |

| | | |
|---|---|---|
| | Insufficient sample. | Repeat the test and apply enough sample to fill the test strip check window. |
| | Running out of battery. | Charge the battery. |
| | Data not transmitted | Please check network connection. Then discard the test strip and repeat the test with a new test strip. If the problem continues, contact 24/7 MIO Customer Support at (833)445-5666 |
| | No signal | Restart the meter. If the problem continues, contact 24/7 MIO Customer Support at (833)445-5666. |
| | The test result is above 600 mg/dL. | Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes “HI”, contact your healthcare professional as soon as possible. |
| | The test result is below 20 mg/dL. | Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes “LO”, contact your healthcare professional as soon as possible. |

# CHAPTER 5: TECHNICAL INFORMATION

## System Specifications：

| Feature | Specification |
|---|---|
| Measurement Range | 20 - 600 mg/dL |
| Measurement Result | Plasma Glucose |
| Sample | Fresh capillary whole blood |
| Sample Volume | 0.8 μL |
| Test Time | 5 seconds |
| Power Source | Rechargeable 3.7 Volt Lithium Ion Battery |
| Charging Time | ≤ 3h, ⎓ Direct current |
| Battery Type | Rechargeable, 1080 mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage) |
| Unit of Measure | mg/dL |
| Memory | 500 records |
| Automatic Shutoff | 2 minutes after last action |
| Dimensions | 97.9 mm x 60.5 mm x 20.3 mm |
| Display Size | 47 mm x 37.5 mm |
| Weight | Approximately 80g |
| Operating Temperature | 41 - 113℉ |
| Operating Relative Humidity | 10-90% (non-condensing) |
| Hematocrit Range | 20 - 70% |
| Charging Port | Type-C |
| Data Transmission | 4G |

## 4G Specifications：

| Item Name | Design Specification |
|---|---|
| Throughput | Downlink≥500Kbps, Uplink≥1000Kbps |
| Latency | ≤25ms |
| Data Integrity | Data shall be transmitted correctly and completely |
| Accessibility | Accessibility is high since 4G is broadband |
| Signal Priority | Routine priority using 4G access standard |

**Warranty**
Please complete the warranty card that came with this product and mail it to

**Mio Labs Inc.**
**#1023, ZGC Innovation Center,**
**4500 Great America Pkwy, Santa Clara, CA 95054**

If the meter fails to work for any reason other than obvious abuse within the first five (5) years from purchase, we will replace it with a new meter free of charge. For your records, also write the purchase date of your product here.
Date of purchase: _____

***Note*:**
*This warranty applies only to the meter in the original purchase, and does not apply to the battery supplied with the meter.*

## EMC Guidance

**Warning:** Don't use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

**Warning:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

**Warning:** Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

**Warning:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 in (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

| **Guidance and Manufacturer's Declaration – Electromagnetic Emissions** | |
|---|---|
| **Emissions test** | **Compliance** |
| RF emissions<br>CISPR 11 | Group 1 |
| RF emissions<br>CISPR 11 | Class B |
| Harmonic emissions<br>IEC 61000-3-2 | Class A |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3 | Complies |

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity | | |
|---|---|---|
| **Immunity Test** | **IEC 60601-1-2 Test Level** | **Compliance Level** |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ±8 kV contact<br>±2 kV, ±4kV, ±8 kV, ±15 kV air | ±8 kV contact<br>±2 kV, ±4kV, ±8 kV, ±15 kV air |
| Electrical fast transient/burst<br>IEC 61000-4-4 | ±2 kV for power supply lines | ±2 kV for power supply lines |
| Surge<br>IEC 61000-4-5 | ± 0.5 kV, ± 1 kV line(s) to line(s) | ± 0.5 kV, ± 1 kV line(s) to line(s) |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | 0 % $U_T$; 0.5 cycle<br>at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°<br><br>0 % $U_T$ ; 1 cycle<br>70 % $U_T$; 25/30 cycle<br>Single phase: at 0°<br>0% $U_T$; 250/300 cycle | 0 % $U_T$; 0.5 cycle<br>at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°<br><br>0 % $U_T$ ; 1 cycle<br>70 % $U_T$; 25/30 cycle<br>Single phase: at 0°<br>0% $U_T$; 250/300 cycle |
| Power frequency magnetic field<br>IEC 61000-4-8 | 30 A/m<br>50Hz/60Hz | 30 A/m<br>50Hz/60Hz |
| Conduced RF<br>IEC61000-4-6 | 3 V r.m.s.<br><br>150 kHz to 80 MHz<br><br>6 V RMS in the ISM and amateur bands between 0.15 MHz and 80 MHz | 3 V r.m.s.<br><br>150 kHz to 80 MHz<br><br>6 V RMS in the ISM and amateur bands between 0.15 MHz and 80 MHz |
| Radiated RF<br>IEC61000-4-3 | 10 V/m<br>80 MHz – 2.7 GHz<br>80 % AM at 1 kHz | 10 V/m<br>80 MHz – 2.7 GHz<br>80 % AM at 1 kHz |
| NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level. | | |

| Guidance and Manufacturer's Declaration - IMMUNITY to proximity fields from RF wireless communications equipment | | | | | |
|---|---|---|---|---|---|
| **Immunity Test** | **IEC60601 Test Level** | | | | **Compliance Level** |
| | **Test Frequency** | **Modulation** | **Maximum Power** | **Immunity Test Level** | |
| Radiated RF IEC 61000-4-3 | 385 MHz | **Pulse Modulation: 18Hz | 1.8W | 27 V/m | 27 V/m |
| | 450 MHz | *FM+ 5 kHz deviation: 1kHz sine | 2 W | 28 V/m | 28 V/m |
| | 710 MHz<br>745 MHz<br>780 MHz | **Pulse Modulation: 217Hz | 0.2 W | 9 V/m | 9 V/m |
| | 810 MHz<br>870 MHz<br>930 MHz | **Pulse Modulation: 18Hz | 2 W | 28 V/m | 28 V/m |
| | 1720 MHz<br>1845 MHz<br>1970 MHz | **Pulse Modulation: 217Hz | 2 W | 28 V/m | 28 V/m |
| | 2450 MHz | **Pulse Modulation: 217Hz | 2 W | 28 V/m | 28 V/m |
| | 5240 MHz<br>5500 MHz<br>5785 MHz | **Pulse Modulation: 217Hz | 0.2 W | 9 V/m | 9 V/m |
| Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.<br><br>Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal. | | | | | |

Frequency Requirement

| Frequency Band | Transmit (MHz) | Receive (MHz) |
|---|---|---|
| Band 2 | 1850 - 1910 | 1930 - 1990 |
| Band 4 | 1710 -1755 | 2110 - 2155 |
| Band 12 | 699 - 716 | 729 - 746 |
| Band 13 | 777 - 787 | 746 - 756 |

TX POWER

| Frequency Band | Max Power | Min Power |
|---|---|---|
| Band 2/4/12/13 | 21 dBm +1.7/-3 dB | < -39 dBm |

## FCC Requirement

RF Exposure Compliance

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End user must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The portable device is designed to meet the requirements for exposure to radio waves established by the Federal Communications Commission (USA). These requirements set a SAR limit of 1.6 W/kg averaged over one gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the extremity, with 00mm separation.