

PLUS Mini

BLOOD GLUCOSE MONITORING SYSTEM

Version 1.0
2018/02



OPERATION INSTRUCTION

IMPORTANT SAFETY INSTRUCTIONS

Read Before Use

Dear owner of PLUS Mini Blood Glucose Monitoring System, The system consists of three main products: the meter, test strips and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Only use PLUS test strips and control solutions with the PLUS Mini Blood Glucose Monitoring System.

Intended Use

This system is intended for external use (*in vitro* diagnostic use) only. It is used for the quantitative measurement of glucose in samples of fresh capillary whole blood taken from the finger, palm, forearm and upper arm. It is not intended to diagnose or screen for diabetes mellitus, or to be used on neonates.

Professionals may test with capillary and venous blood sample; home use is limited to capillary whole blood testing.

This system provides you with plasma equivalent results.

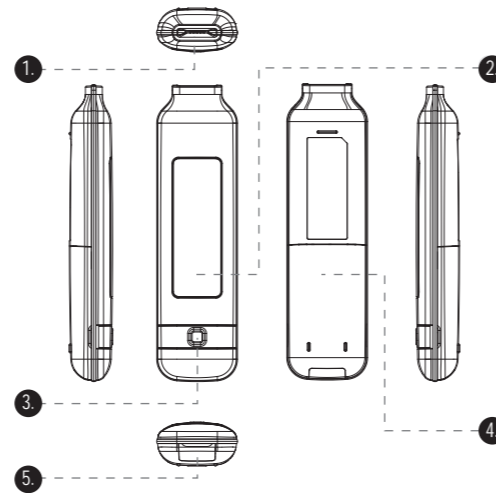
The measurement unit used for indicating the concentration of blood or plasma glucose can either have a weight dimension (mg/dL) or a molarity (mmol/L). The approximate calculation rule for conversion of mg/dL in mmol/L is:

mg/dL	Divided by 18	= mmol/L
mmol/L	Times 18	= mg/dL

For example:
1) 120 mg/dL ÷ 18 = 6.6 mmol/L
2) 7.2 mmol/L x 18 = 129 mg/dL approximately.

APPEARANCE AND KEY FUNCTIONS OF THE METER

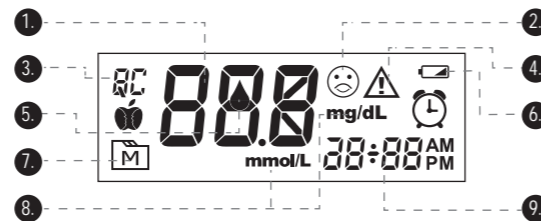
1. Test Strip Slot
2. Display Screen
3. Main Button
4. SET Button
5. Data Port



NOTE

The meter will turn off automatically after 120 seconds without any action or you can press and hold the main button for 3 seconds to turn off the meter.

METER DISPLAY

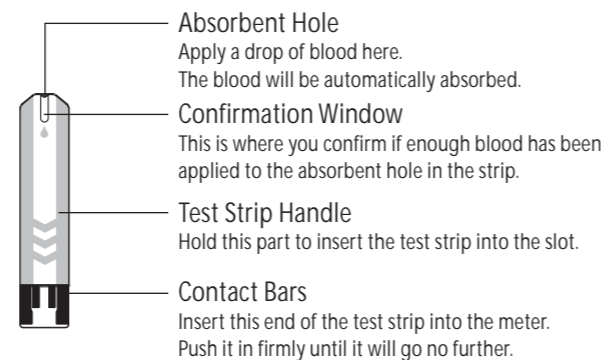


1. Test Result
2. Face/ Low/ High Symbol
3. Measuring Mode
4. Error Message
5. Blood Drop Symbol
6. Low Battery Symbol
7. Memory Mode Symbol
8. Measurement Unit
9. Time/Date

PLUS TEST STRIPS

Your system measures the amount of sugar (glucose) in whole blood. Blood is applied to the absorbent hole on the test strip and is automatically drawn into the reaction cell where the reaction takes place.

The test strip consists of the following parts:

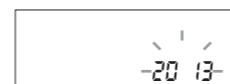


SETTING THE METER AND DELETING THE MEMORY

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

STEP 1. Setting the date

With the year flashing, press Main button until the correct year appears. Press SET.



With the month flashing, press Main button until the correct month appears. Press SET.



With the day flashing, press Main button until the correct day appears. Press SET.



STEP 2. Setting the time format

Press Main button to select the desired time format -- 12h or 24h. Press SET.



STEP 3. Setting the time

With the hour flashing, press Main button until the correct hour appears. Press SET.
With the minute flashing, press Main button until the correct minute appears. Press SET.



STEP 4. Setting the unit of measurement

Press Main button to switch between mg/dL and mmol/L. Press SET.



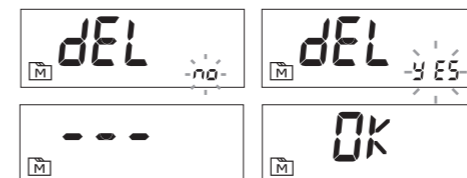
STEP 5. Setting the buzzer

With the buzzer displays, press Main button to switch between "On" and "OFF". Press SET.



STEP 6. Deleting the memory

With "dEL" and a flashing "M" on the display, press Main button and select "no" to keep the results in memory then press SET to skip.
To delete all the results, press Main button and "yes" and "M" are displayed on the meter, press SET to delete the memory.



If you do not want to delete the results, do not press the main button but press the setting button again to turn off the meter.

THE FOUR MEASURING MODES

The meter provides you with four modes for measuring, General, AC, PC and QC.

MODES	USE WHEN
General	any time of day without regard to time since last meal
AC	no food intake for at least 8 hours
PC	2 hours after a meal
QC	testing with the control solution

You can switch between each mode by:

1. Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display "▲".



2. Press Main button to switch between General, AC, PC and QC mode.



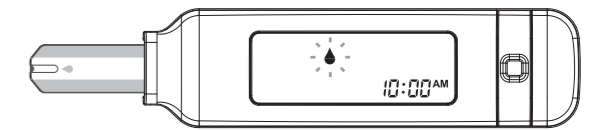
CHECKING THE SYSTEM WITH CONTROL SOLUTIONS

Our control solutions contain a known amount of glucose that reacts with test strips. By comparing the result of your control solution test with the expected range printed on the test strip vial label, you can check that the meter and the test strips are working together as a system and that you are performing the test correctly. It is very important that you perform this simple check routinely to make sure you get accurate results.

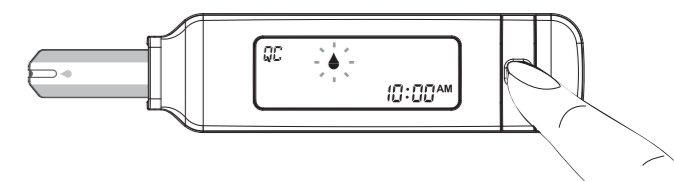
HOW TO PERFORM A CONTROL SOLUTION TEST

STEP 1. Insert test strip

Insert a test strip into the test slot with the contact bars end first and facing up. (Contact bars must be inserted all the way into the meter or you may get an inaccurate test result.) The meter turns on automatically and displays the following in sequence:



When the "▲" symbol appears on the display, press Main button and "QC" will appear on the display. When the "QC" sign is displayed, the meter will not store your test result in the memory. If you decide not to perform a control solution test, press Main button again and the "QC" sign will disappear.

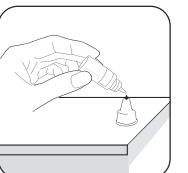


CAUTION

Every time you perform a control solution test you must enter "QC" test mode so that the test result will not be stored in the meter memory.

STEP 2. Apply control solution

Shake the control solution vial thoroughly before use. Squeeze out a drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap. Hold the meter to move the absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will begin counting down. To avoid contaminating the control solution, do not directly apply control solution onto a strip.



STEP 3. Read and compare the results

After the meter counts to 0, the result of the control solution test will appear. Compare the result with range printed on the test strip vial. The result should fall within this range.



Out-of-range results

If you continue to have test results fall outside the range printed on the test strip vial, the meter and strips may not be working properly. Do NOT test your blood. Contact the local customer service or place of purchase for help.

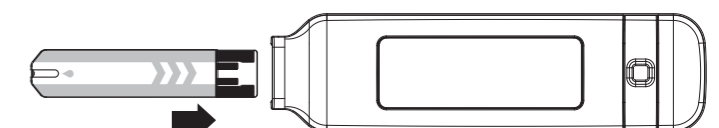
TESTING YOUR BLOOD

Preparing the Lancing Device for Blood Testing

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

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

Wait for the meter to display "▲".



STEP 2. Select the appropriate measuring mode by pressing Main button

For selecting the measurement mode, please refer to the "FOUR MEASURING MODES".

WARRANTY CERTIFICATE

YEAR WARRANTY

Owner's portion

Name of product: _____

Name of owner: _____

Address: _____

Tel No: (Mobile) _____ (H) _____ (O) _____

Email: _____ Age: _____ Gender: M F

Date of Purchase: / /
day month year

Dealer's Stamp:

Serial No.: _____

*NOTE: Please produce this card together with the purchase receipt for warranty service.

WARRANTY REGISTRATION CARD

Dealer's portion

Name of product: _____

Name of owner: _____

Address: _____

Tel No: (Mobile) _____ (H) _____ (O) _____

Email: _____ Age: _____ Gender: M F

Date of Purchase: / /
day month year

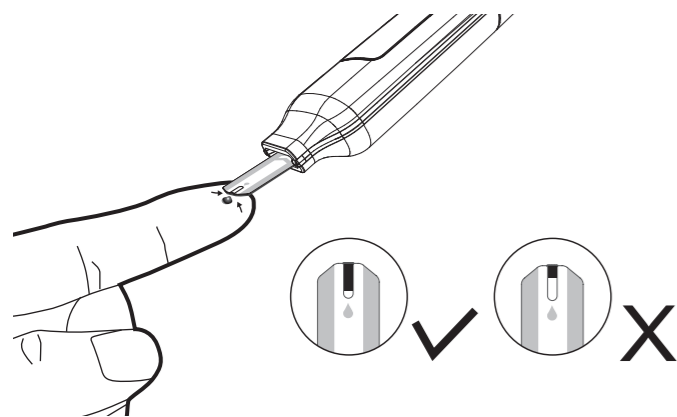
Dealer's Stamp:

Serial No.: _____

*IMPORTANT: To qualify for the warranty, please fill in this card and mail to us within 14 days from the date of purchase.

STEP 3. Apply blood sample

Obtain a drop of blood of at least 0.5 µL using a lancing device. Use the clear cap for sites other than fingers and refer to the strip package insert for more details.



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

If the confirmation window is not filled completely before the meter begins to count down, do not add more blood to the test strip. Discard the test strip and start again. If you have trouble filling the test strip, please call your local customer service number for assistance.

NOTE

If you do not apply a blood sample within 2 minutes, the meter will turn itself off. You must remove the test strip and insert it back into the meter to restart the test.

STEP 4. Get result

The blood glucose result will be stored in the memory automatically. (100 mg/dL = 5.5 mmol/L)



Warning:

- Please do not change your treatment based on the result without first consulting your health care professional.
- Turn the meter off by removing the test strip. Discard the used test strip and lancet carefully according to your local regulations.

VIEWING THE METER MEMORY

Viewing Results

Your Meter stores the 150 most recent blood glucose test results with date and time in its memory. You can review the test results with these easy steps.

STEP 1. Enter the memory mode

With the meter turned off, press Main button twice. The first test result will appear, indicating that you are in the memory mode.



When using the meter for the first time or if the results have been deleted, "—" will appear, indicating that there are no test results in the memory.



STEP 2. Recall test results

If you continue to press Main button, you can then review the last 150 tests in the memory. (300 mg/dL = 16.7 mmol/L; 200 mg/dL = 11.1 mmol/L)



STEP 3. Exit the memory mode

After displaying the last test result in memory, press the Main button again. The meter displays "End" and then turns off.



NOTE

- If you wish to exit memory mode before the last result being displayed, press the main button for 3 seconds.
- When the memory is full, the oldest test result will be replaced by the newest test result.
- The control solution results are NOT stored in the memory. Only blood glucose results will be stored.

DOWNLOADING RESULTS ONTO A COMPUTER

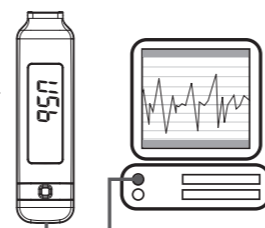
You can use the meter with a USB cable and the Health Care Software System to view your test results on your personal computer. To learn more about the Health Care Software System or to obtain a USB cable separately, please contact local customer services or the place of purchase for assistance.

1. Obtaining the required cable and installing the software

To download the Health Care Software System, please visit TaiDoc website at <http://www.Taidoc.com>

2. Connecting to a personal computer

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



3. Data transmission

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

Warning:

While the meter is connecting to the PC, it will be unable to perform a blood glucose test.

DISPLAY MESSAGES AND PROBLEM-SOLVING GUIDE

The following is a summary of display messages. If your meter displays an error message, please follow the actions for the error message as described in the table below. If the problem persists, please contact your local customer service agent for help.

MESSAGE	WHAT IT MEANS		
Lo	< 20 mg/dL (1.1 mmol/L)		
☹	20 - 69 mg/dL (1.1 - 3.8 mmol/L)		
☺	 70 - 129 mg/dL (3.8 - 7.1 mmol/L)	 70 - 179 mg/dL (3.8 - 9.9 mmol/L)	General 70 - 119 mg/dL (3.8 - 6.6 mmol/L)
☹	 130 - 239 mg/dL (7.2 - 13.2 mmol/L)	 180 - 239 mg/dL (10 - 13.2 mmol/L)	General 120 - 239 mg/dL (6.6 - 13.2 mmol/L)
☹	≥ 240 mg/dL (13.3 mmol/L)		
Hi	> 600 mg/dL (33.3 mmol/L)		

MESSAGE	WHAT IT MEANS	ACTION
E-b	Appears when the batteries are too low.	Replace or recharge the battery immediately.
E-U	Appears when a used test strip is inserted.	Repeat test with a new test strip.
E-t	Appears when ambient temperature is above / below system operation range.	System operation range is 10°C to 40°C (50°F to 104°F). Repeat the test after the meter and test strip are in the above temperature range.
E-E	Problem with the meter.	Repeat the test with a new test strip. If the meter still does not work, please contact the customer service for assistance.
E-D		
E-R		
E-C		
E-F	Appears when test strip is removed while counting down, or insufficient blood volume.	Review the instructions and repeat test with a new strip. If the problem persists, please contact the local customer service for help.

For questionable results, please see test strip package insert for important information.

SYMBOL INFORMATION

Symbol	Referent	Symbol	Referent
IVD	In vitro diagnostic medical device	Manufacturer logo	Manufacturer
Book icon	Consult instructions for use	SN	Serial number
Temperature icon	Temperature limitation	ECI REP	Authorized representative in the European Community
Use by icon	Use by	LOT	Batch code

SPECIFICATIONS

Model no.: PLUS Mini

Dimension: 103.4 (L) x 28.1 (W) x 15.1 (H) mm

Weight: 31.8g

Power source: CR2032

Display: LCD

Memory: 150 memory sets with date and time

Auto electrode insertion detection

Auto reaction time count-down

Auto switch-off after 2 minutes without action

Temperature Warning

Auto sample loading detection

Operating conditions: 10°C to 40°C (50°F to 104°F), 10% - 85% R.H.

Meter Storage/Transportation Conditions: -20°C to 60°C (-4°F to 140°F), 10% - 95% R.H.

Strip Storage/Transportation Conditions: 2°C to 30°C (35.6°F to 86°F), 10% - 85% R.H.

Measurement units: either mg/dL or mmol/L

Measurement range: 20-600 mg/dL (1.1-33.3 mmol/L)

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

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www.taidoc.com

MedNet GmbH
Borkstraße 10, 48163 Münster, Germany



TERMS & CONDITIONS OF WARRANTY

1. We warrant this product to be free of defects in workmanship and materials within the said warranty period on the warranty certificate.
2. During the warranty period, if this product is found to be defective, you may bring it, together with the purchase receipt and Warranty Certificate, on a carry-in basis to our office during normal business hours for warranty service. We will then repair or replace defective parts or exchanging the whole product as we may choose, at no charge to the original owner. After such repair, replacement or exchange, the product will be warranted for up to the remainder of the warranty period.
3. This warranty is valid only if the Warranty Certificate and Warranty Registration Card are duly completed with date of purchase, serial number and dealer's stamp, and if the Warranty Registration Card is sent to our office not later than 14 days from the date of purchase.
4. This warranty is void if this product has been repaired or serviced by unauthorized person. This warranty does not cover defects caused by misuse, abuse, accident, tampering, lack of reasonable care, fire or any other acts beyond human control.
5. Except as stated in the above paragraphs, we disclaim all other warranties, implied or expressed, including the warranties of merchantability or fitness for a particular purpose with respect to the use of this product. We shall not be liable for any direct, consequential or incidental damages arising out of the use or inability to use this product.

PLEASE
AFFIX
STAMP

DEALER'S INFORMATION