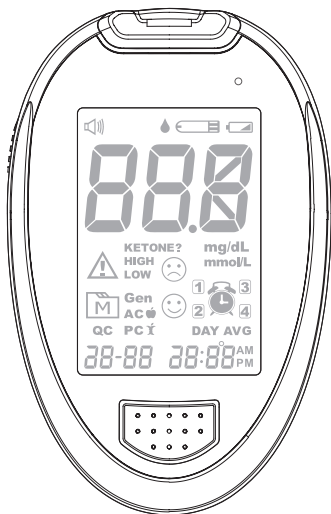# PLUS One

Blood Glucose Monitoring System

Owner's Manual

Dear PLUS One System Owner:

Thank you for purchasing the **PLUS One** Blood Glucose Monitoring System. This manual provides important information to help you to use the system properly. Before using this product, please read the following contents thoroughly and carefully.

Regular monitoring of your blood glucose levels can help you and your doctor gain better control of your diabetes. Due to its compact size and easy operation, you can use the **PLUS One** Blood Glucose Monitoring System to easily monitor your blood glucose levels by yourself anywhere, any time.

If you have other questions regarding this product, please contact the local customer service or place of purchase.

Intended Use
This system is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and by health care professionals in clinical settings as an aid to monitoring the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) in fresh whole blood samples (from the finger, palm, forearm and upper arm), and from venous whole blood.

It should not be used for the diagnosis or screening of diabetes.

Professionals may test with capillary and venous blood sample; home use is limited to capillary whole blood testing.
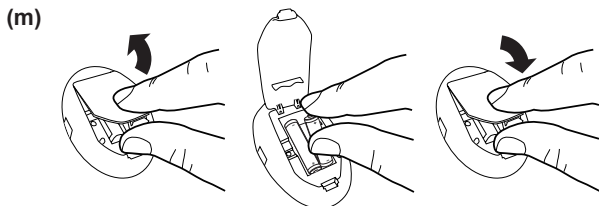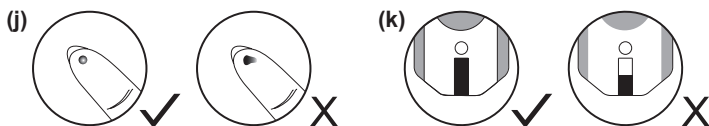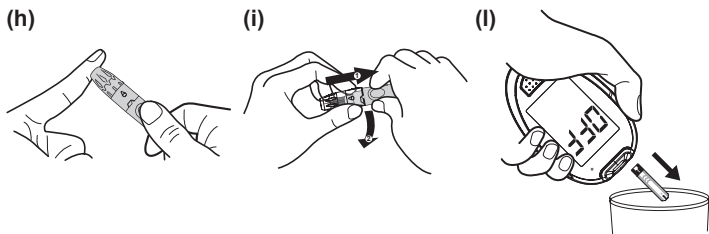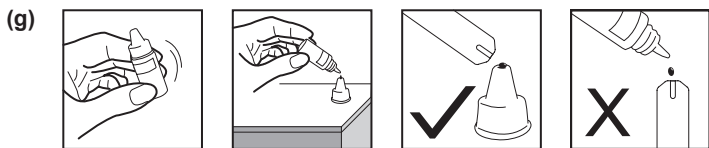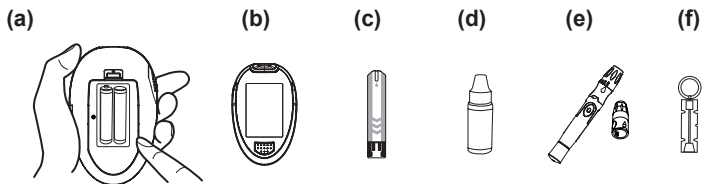
IMPORTANT SAFTY INSTRUCTIONS
READ BEFORE USE

1. Use this device **ONLY** for the intended use described in this manual.
2. Do **NOT** use accessories which are not specified by the manufacturer.
3. Do **NOT** use the device if it is not working properly or if it is damaged.
4. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only. Always consult your doctor to have the results interpreted.
5. Before using this device to test blood glucose, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
6. Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
7. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
8. Do **NOT** use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
9. Proper maintenance and periodically control solution test are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact the local customer service or place of purchase for help.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

TABLE OF CONTENTS

(a) **(b)** **(c)** **(d)** **(e)** **(f)**

(g)

(h) **(i)** **(l)**

(j) **(k)**

(m)

BEFORE YOU BEGIN

Important Information

- Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- If your blood glucose results are lower or higher than usual, and you do not have any symptoms of illness, first repeat the test. If you have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of your healthcare professional.
- Use only fresh whole blood samples to test your blood glucose. Using other substances will lead to incorrect results.
- If you are experiencing symptoms that are inconsistent with your blood glucose test results and you have followed all the instructions given in this owner's manual, contact your healthcare professional.
- We do not recommend using this product on severely hypotensive individuals or patients in shock. Please consult the healthcare professional before use.
- 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:
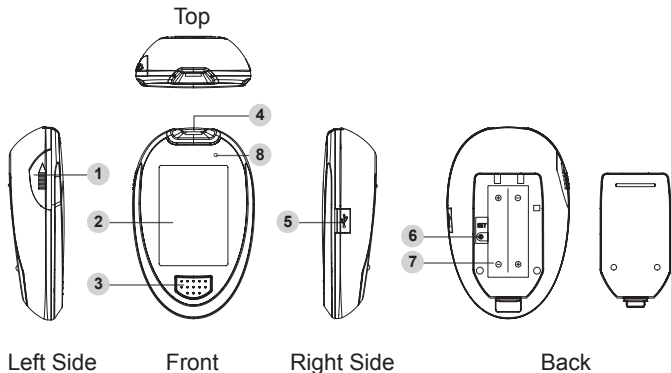
mg/dL	Divided by 18	= mmol/L
mmol/L	Times 18	= mg/dL

For example:

1) 120 mg/dL ÷ 18 = 6.6 mmol/L

2) 7.2 mmol/L x 18 = 129 mg/dL approximately.

Meter Overview

Top

Left Side   Front   Right Side   Back

1. **Test Strip Ejector**
   Eject the used strip by pushing up this button.

2. **Display Screen**

3. **Main Button (M)**
   Enter the meter memory and silence a reminder alarm.

4. **Test Strip Slot with Strip Indication Light**
   Insert test strip here to turn the meter on for testing.

5. **Data Port (for PLUS One with USB cable)**
   Download test results with a cable connection.

6. **SET Button (S)**
   Enter and confirm the meter settings.

7. **Battery Compartment**

8. **Bluetooth Indication Light (for PLUS One with Bluetooth)**

Display Screen

1 **Test Result**

2 **Ketone Warning**

3 **Error Warning**

4 **Memory Symbol**

5 **Control Solution Mode**
   QC – control solution test

6 **Measuring Mode**
   AC – before meal
   PC – after meal
   Gen – any time of day

7 **Date**

8 **Time**

9 **Day Average**

10 **Alarm Symbol**

11 **Face/Low/High Symbol**

12 **Measurement Unit**

13 **Low Battery Symbol**

14 **Test Strip Symbol**

15 **Blood Drop Symbol**

16 **Buzzer**
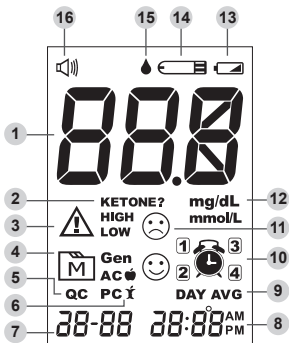
Test Strip
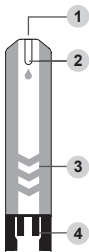
1 **Absorbent Hole**

2 **Confirmation Window**

3 **Test Strip Handle**

4 **Contact Bars**

ATTENTION:

The front side of test strip should face up when inserting test strip. Test results might be wrong if the contact bar is not fully inserted into the test slot.

NOTE:

The **PLUS One** monitor should only be used with **PLUS** Test Strips. Using other test strips with this meter can produce inaccurate results.

SETTING THE METER

Before using your meter for the first time or if you change the meter battery, you should check and update these settings.

Entering the Setting Mode (a)
Start with the meter off (no test strip inserted). Press **S**.

1. Setting the date
The sequence of the date setting is: YEAR → MONTH → DAY. With the YEAR / MONTH / DAY flashing in sequence, press **M** until the correct year/month/day appears. Press **S**.

2. Setting the time format
Press **M** to select the desired time format --- 12h or 24h. Press **S**.

3. Setting the time
With the HOUR / MINUTE flashing in sequence, press **M** until the correct hour/minute appears. Press **S**.

4. Setting the unit of measurement
Press **M** to switch between mg/dL and mmol/L. Press **S**.

5. Setting the buzzer
With the buzzer displays, press **M** to switch between "On" and "OFF". Press **S**.

6. Deleting the memory
With "dEL" and a flashing " 🗑 " on the display, press **M** and select "no" to keep the results in memory then press **S** to skip. To delete all the results, press **M** and select "yes" to delete all the memory records.

7. Setting the reminder alarm
Your meter has four reminder alarms. The meter will display "OFF" and " ¹🔔 ". If you don't want to set an alarm, press **S** to skip this step. Or press **M** to select "On", then press **S**.

With the hour/minute flashing in sequence, press **M** to select the correct hour/minute. Press **S** and go to the next alarm setting.

NOTICE:
When the alarm beeps, press **M** to switch it off. Otherwise, it will beep for 2 minutes then switch off.

Congratulations! You have completed all settings!

NOTE:
- These parameters can **ONLY be changed** in the setting mode.
- If the meter is idle for 3 minutes during the setting mode, it will switch off automatically.

THE FOUR MEASURING MODES

The meter provides you with four modes for measuring, General, AC, PC and QC. 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 a flashing " 💧 " and "Gen".

2. Press **M** to switch between General, AC, PC and QC mode.

__QUALITY CONTROL TESTING__

When Should the Control Solution Test be Performed?

● if it is mandatory following the local regulations in your country,
● if you suspect the meter or test strips are not working properly,
● if your blood glucose test results are not consistent with how you feel, or if you think the results are not accurate,
● to practice the testing process, or
● if you have dropped or think you may have damaged the meter.

Test strips **(c)**, control solutions **(d)**, lancing device **(e)** or sterile lancets **(f)** may not be included in the kit (please check the contents on your product box). They can be purchased separately. Please make sure you have those items needed for a blood glucose test beforehand.

Performing a Control Solution Test

To perform a control solution test, you will need: **(b)**, **(c)** and **(d)**.

1. Insert the test strip to turn on the meter

Insert the test strip into the meter. Wait for the meter to display " ⬒ " and " ⬥ ".

2. Press M to mark this test as a control solution test

With " **QC** " displayed, the meter will store your test result in memory under " **QC** ". If you press **M** again, the " **QC** " will disappear and this test is no longer a control solution test.

WARNING:

When doing the control solution test, you have to mark it so that the test result will **NOT** mix with the blood glucose **TEST RESULTS** stored in the memory. Failure to do so will mix up the blood glucose test results with the control solution test results in memory.

3. Apply control solution (g)

Shake the control solution vial thoroughly before use. Squeeze out first 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.

NOTICE:

To avoid contaminating the control solution, do not directly apply control solution onto a strip.

4. Read and compare the result

After counting down to 0, the control solution test result will appear on the display. Compare this result with the range printed on the test strip vial and it should fall within this range. If not, please read the instructions again and repeat the control solution test.

NOTE:

- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose level.
- See the **MAINTENANCE** section for important information about your control solutions.

<u>TESTING WITH BLOOD SAMPLE</u>

WARNING:

To reduce the chance of infection:

- Never share a lancet or the lancing device.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.

Preparing the Lancing Device for Blood Testing

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

Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction has a significant influence on the glucose value obtained. Blood from a site that has not been rubbed exhibits a measurably different glucose concentration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

Please follow the suggestions below before obtaining a drop of blood:

- **Wash and dry your hands before starting.**
- Select the puncture site either at fingertips or another body parts (please see section "Alternative Site Testing" (AST) on how to select the appropriate sites).
- Rub the puncture site for about 20 seconds before penetration.
- Clean the puncture site using cotton moistened with 70% alcohol and **let it air dry**.
- Use a clear cap (included in the kit) while setting up the lancing device.

● **Fingertip testing (h)**
Press the lancing device's tip firmly against the lower side of your fingertip. Press the release button to prick your finger, then a click indicates that the puncture is complete.

● **Blood from sites other than the fingertip (i)**
Replace the lancing device cap with the clear cap for AST. Pull the cocking control back until it clicks. When lancing the forearm, upper arm, or hand, avoid lancing the areas with obvious veins because of excessive bleeding.

NOTE:
- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- Please consult your health care professional before you begin AST.

Performing a Blood Glucose Test

To perform a blood glucose test, you will need: **(b)**, **(c)**, **(e)** and **(f)**.

1. Insert the test strip to turn on the meter
Wait for the meter to display " ⬚ " and " 🌢 ".

2. Select the appropriate measuring mode by pressing M

3. Obtaining a blood sample (j)
Use the pre-set lancing device to puncture the desired site. The size of the drop should be at least as big as ◦ (actual size), which is **0.5** microliter (µL) of volume. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample.

4. Apply the sample (k)
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.

5. Read your result

The result of your blood glucose test will appear after the meter counts down to 0. The blood glucose result will be stored in the memory automatically.

6. Eject the used test strip (l)

Eject the test strip by pushing the eject button on the side. Use a sharp bin to dispose of used test strips. The meter will switch itself off automatically.

Always follow the instructions in the lancing device insert when removing the lancet.
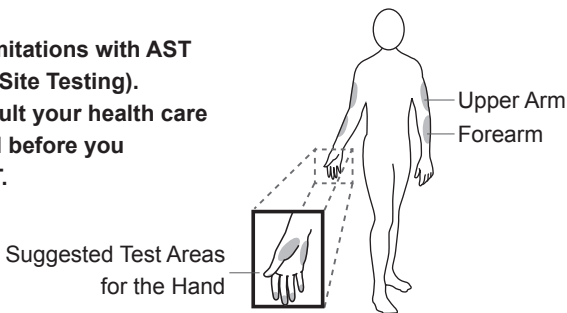
Alternative Site Testing
You can test on a variety of locations on your body.

Important:
There are limitations with AST (Alternative Site Testing). Please consult your health care professional before you perform AST.

Upper Arm
Forearm

Suggested Test Areas
for the Hand

When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at the fingertip reflects these changes faster than capillary blood at other sites. Thus, when testing blood glucose during or immediately after a meal, physical exercise, or any other event, **take a blood sample from your finger only.**

We strongly recommend that you perform AST **ONLY** at the following times:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

Do **NOT** use AST if:

- You think your blood glucose is low.
- You are unaware of hypoglycemia.
- You are testing for hyperglycemia.
- Your AST results do not match the way you feel.
- Your routine glucose results often fluctuate.

METER MEMORY

The meter stores the **1000** most recent blood glucose test results along with respective dates and times in its memory. To enter the meter memory, **start with the meter switched off.**

Reviewing Test Results

1. Press and release M.

" Ⓜ " will appear on the display. Press **M** again, and the first reading you see is the last blood glucose result along with date, time and the measuring mode.

2. Press M to recall the test results stored in the meter each time you press. **After the last test result, press M again and the meter will be turned off.**

Reviewing Blood Glucose Day Average Results

1. Press and release M. When " Ⓜ " appears on the display, keep pressing M for 3 seconds until the flashing " **DAY AVG** " appears. Release **M** and then your 7-day average result measured in general mode will appear on the display.

2. Press M to review 14-, 21-, 28-, 60- and 90- day average results stored in each measuring mode in the order of Gen, AC, then PC.

3. Exit the meter memory. Keep pressing the **M** and the meter will turn off after displaying the last test result.

NOTE:

- Any time you wish to exit the memory, keep pressing **M** for 5 seconds or leave it without any action for 3 minutes. The meter will switch off automatically.
- Control solution results are **NOT** included in the day average.

DOWNLOADING RESULTS ONTO A COMPUTER

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

1. Obtaining the required cable and installing the software
To download Health Care Software System, please visit the TaiDoc's website: 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.

__BLUETOOTH PAIRING__

Data Transmission Via Bluetooth (for PLUS One with Bluetooth)
You can transmit your data from the meter to your device via
Bluetooth. Please contact your local customer service or place of
purchase for assistance. Please note that you must complete the
pairing between meter and Bluetooth receiver before transmitting data.

Pairing with your mobile device
1. Turn on the Bluetooth function on your mobile device.
2. After the end of measuring mode or memory mode, "OFF" is shown
on the display of the meter. The Bluetooth indicator will turn to flash
which means that the Bluetooth of meter is turned on automatically.
3. Follow the instruction of your APP to pair the device. (Ex. Search to
find the meter and then add it into app.)
4. After successfully pairing the APP with the device, the Bluetooth
function of meter shall be on before transmitting the data to your APP.

Bluetooth Indicator on the Blood Glucose Meter:

BLUETOOTH INDICATOR	STATUS
Flashing Blue	The Bluetooth function is on and waiting for connection.
Solid Blue	The Bluetooth connection is established.

NOTE:
- While the meter is in transmission mode, it will be unable to perform a test.
- Make sure your device support Bluetooth Smart Technology has turned on Bluetooth before transmitting the data and the meter is within the receiving range. For the requirement of OS version, please find on App Store or Google Play when you download the app.
- The Bluetooth functionality is implemented in different ways by the various mobile device manufacturers, the compatibility issue between your mobile device and the meter maybe occur.

MAINTENANCE

Battery

Your meter comes with two 1.5V AAA size alkaline batteries.

Low Battery Signal

The meter will display one of the messages below to alert you when the meter power is getting low.

1. The " " symbol appears along with display messages: The meter is functional and the result remains accurate, but it is time to change the batteries.

2. The " " symbol appears with E-b, Error and low: The power is not enough to do a test. Please change the batteries immediately.

Replacing the Battery (m)

To replace the batteries, make sure the meter is turned off.

1. Press the edge of the battery cover and lift it up to remove.

2. Remove the old batteries and replace with two 1.5V AAA size alkaline batteries.

3. Close the battery cover. If the batteries are inserted correctly, you will hear a "beep" afterwards.

NOTE:

- Replacing the batteries does not affect the test results stored in the memory.
- As with all small batteries, these batteries should be kept away from children. If swallowed, promptly seek medical assistance.
- Batteries might leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more).
- Properly dispose of the batteries according to your local environmental regulations.

Caring for Your Meter

Cleaning

- To clean the meter exterior, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do **NOT** rinse with water.
- Do **NOT** use organic solvents to clean the meter.

Meter Storage

- Storage conditions: -20°C to 60°C (-4°F to 140°F), 10% - 95% relative humidity.
- Always store or transport the meter in its original storage case.
- Avoid dropping and heavy impact.
- Avoid direct sunlight and high humidity.

Meter Disposal

The used meter should be treated as contaminated that may carry a risk of infection during measurement. The batteries in this used meter should be removed and the meter should be disposed in accordance with local regulations.

The meter falls outside the scope of the European Directive 2002/96/EC-Directive on waste electrical and electronic equipment (WEEE).

Caring for Your Test Strips

- Storage conditions: 2°C to 30°C (35.6°F to 86°F), 10% - 85% relative humidity. Do **NOT** freeze.
- Store your test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately close the vial cap tightly.
- Touch the test strip with clean and dry hands.

- Use each test strip immediately after removing it from the vial.
- Write the opening date on the vial label when you first opened it. Discard remaining test strips after 6 months.
- Do not use test strips beyond the expiry date. This may cause inaccurate results.
- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

For further information, please refer to the test strip package insert.

Important Control Solution Information

- Use only our control solutions with your meter.
- Do not use the control solution beyond the expiry date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature 20°C to 25°C (68°F to 77°F). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.
- Store the control solution tightly closed at temperatures between 2°C to 30°C (35.6°F to 86°F). Do **NOT** freeze.

<u>SYSTEM TROUBLESHOOTING</u>

If you follow the recommended action but the problem persists, please call your local customer service.

Result Readings

MESSAGE	WHAT IT MEANS		
Lo	< 20 mg/dL (1.1 mmol/L)		
LOW ☹	20 − 69 mg/dL (1.1–3.8 mmol/L)		
☺	**AC**	**PC**	**Gen**
	70 − 129 mg/dL (3.8 − 7.1 mmol/L)	70 − 179 mg/dL (3.8 − 9.9 mmol/L)	70 − 119 mg/dL (3.8 − 6.6 mmol/L)
HIGH ☹	**AC**	**PC**	**Gen**
	130 − 239 mg/dL (7.2 − 13.2 mmol/L)	180 − 239 mg/dL (10 − 13.2 mmol/L)	120 − 239 mg/dL (6.6 − 13.2 mmol/L)
KETONE? HIGH ☹	≥ 240 mg/dL (13.3 mmol/L)		
H i	> 600 mg/dL (33.3 mmol/L)		

Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
E-b	Appears when the batteries are too low.	Replace the batteries immediately.
E-U	Appears when a used test strip is inserted.	Repeat with a new test strip.
E-t	Appears when ambient temperature is above or 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-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.
E-0, E-A, E-C, 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.

Troubleshooting

1. If the meter does not display a message after inserting a test strip:

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Replace the batteries.
Test strip inserted upside down or incompletely.	Insert the test strip with contact bars end first and facing up.
Defective meter or test strips.	Please contact customer services.

2. If the test does not start after applying the sample:

POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off (3 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing " ⬩ " appears on the display.
Defective meter.	Please contact customer services.

3. If the control solution testing result is out of range:

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read instructions thoroughly and repeat the test again.
Control solution vial was poorly shaken.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiry date of the control solution.
Control solution that is too warm or too cold.	Control solution, meter, and test strips should be at room temperature 20°C to 25°C (68°F to 77°F) before testing.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact customer services.
Improper working of meter and test strip.	Please contact customer services.

DETAILED INFORMATION

The meter provides you with plasma equivalent results.

Time of day	Normal plasma glucose range for people **without** diabetes (mg/dL)
Fasting and before meal	< 100 mg/dL (5.6 mmol/L)
2 hours after meals	< 140 mg/dL (7.8 mmol/L)

Source: American Diabetes Association (2014). Clinical Practice Recommendations. Diabetes Care, 37 (Supplement 1): S16.

Please consult your doctor to determine a target range that works best for you.

SYMBOL INFORMATION

SYMBOL	REFERENT	SYMBOL	REFERENT
IVD	*In vitro* diagnostic medical device	▲▲	Manufacturer
📖i	Consult instructions for use	SN	Serial number
🌡	Temperature limitation	EC REP	Authorized representative in the European Community
⎍	Use by	🲥%	Humidity limitation
LOT	Batch code	🗑	Collection for electrical and electronic equipment
CE 0123	CE mark		
⚠	Caution, consult accompanying documents		

SPECIFICATIONS

Model No.: PLUS One
Dimension & Weight: 96 (L) x 61 (W) x 26 (H) mm, 67.2 g
Power Source: Two 1.5V AAA alkaline batteries
Display: LCD
Memory: 1000 measurement results with respective date and time
External Output: USB Cable (for PLUS One with USB cable) or
Bluetooth (for PLUS One with Bluetooth)

Auto electrode insertion detection
Auto sample loading detection
Auto reaction time count-down
Auto switch-off after 3 minutes without action
Temperature Warning

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

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 to 600mg/dL (1.1 to 33.3mmol/L)
Expected Service Life: 5 years

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, IEC/EN 61326-2-6,
EN 301 489-17, EN 301 489-1, EN 300 328.

TaiDoc Technology Corporation
B1-7F, No. 127, Wugong 2nd Rd., Wugu Dist.,
24888 New Taipei City, Taiwan
www.taidoc.com

EC REP **MedNet GmbH**
Borkstraβe 10, 48163 Münster, Germany

For self-testing

$C\epsilon$ 0123 IVD