plusmed
health management

Model: **pM-900**
fasTest **DiagnoPRO**

Multi-Monitoring System
Çoklu Ölçüm Sistemi

TR **Kullanım Kılavuzu**
EN **Instruction Manual**

Multi-Monitoring System

Thank you for choosing PLUSMED fasTTest DiagnoPro Multi-Monitoring System (Model: PM 900). You now have a very simple and accurate way to test your Blood Glucose, β-Ketone and Uric Acid from Fresh Capillary Whole Blood, Arterial or Venous Blood,samples in just a few simple steps anytime, anywhere.

Attention: **PLUSMED fasTTest DiagnoPro Blood Glucose Test Strips with PLUSMED fasTTest DiagnoPro Multi-Monitoring System are intended for *in-vitro* diagnostic self-testing by people with diabetes and healthcare professionals in clinical settings. PLUSMED fasTTest DiagnoPro Blood Ketone Test Strips and PLUSMED fasTTest DiagnoPro Blood Uric Acid Test Strips with PLUSMED fasTTest DiagnoPro Multi-Monitoring System are limited to healthcare professional use only.**

To ensure accurate results from your PLUSMED fasTTest DiagnoPro Multi-Monitoring System, please follow these guidelines carefully:

- Read instructions before use.
- PLUSMED fasTTest DiagnoPro Multi-Monitoring system is intended for *in- vitro* diagnostic use only. It is intended to be used with PLUSMED fasTTest DiagnoPro Blood Glucose Test Strips, PLUSMED fasTTest DiagnoPro Blood β-Ketone Test Strips, and PLUSMED fasTTest DiagnoPro Blood Uric Acid Test Strips to quantitatively measure glucose, β-hydroxybutyrate (β-Ketone), and uric acid from whole blood sample.

  Note: There are two types of PLUSMED fasTTest DiagnoPro blood glucose test strips available, PLUSMED fasTTest DiagnoPro blood glucose test strips using glucose oxidase (GLU GOD) and PLUSMED fasTTest DiagnoPro blood glucose test strips using glucose dehydrogenase FAD-dependent (GLU GDH).

- PLUSMED fasTTest DiagnoPro Multi-Monitoring Meter with PLUSMED fasTTest DiagnoPro Blood Glucose Test Strips are intended for use by people with diabetes mellitus at home and by healthcare professionals in clinical settings as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus.

  Note: When PLUSMED fasTTest DiagnoPro Blood Glucose Test Strips (Glucose Oxidase) are used, only fresh capillary whole blood is allowable to be used for testing. When PLUSMED fasTTest DiagnoPro Blood Glucose Test Strips (Glucose Dehydrogenase FAD-dependent) are used, fresh capillary whole blood, arterial or venous whole blood is allowable to be used for testing, but venous whole blood testing is limited for professional use only.

- PLUSMED fasTTest DiagnoPro Multi-Monitoring Meter with PLUSMED fasTTest DiagnoPro Blood Ketone Test Strips are intended for use for the quantitative measurement of β-hydroxybutyrate (β-Ketone) in fresh capillary whole blood, arterial

or venous whole blood. It should NOT be used to diagnose DKA, and it is limited for professional use only.

- PLUSMED fasTTest DiagnoPro Multi-Monitoring Meter with PLUSMED fasTTest DiagnoPro Blood Uric Acid Test Strips are intended for use for the quantitative measurement of uric acid in fresh capillary whole blood, arterial or venous whole blood, and PLUSMED fasTTest DiagnoPro Multi-Monitoring Meter with PLUSMED fasTTest DiagnoPro Blood Uric Acid Test Strips is limited for professional use only.

- The device should not be used for patients who are dehydrated, in shock, critically ill or in a hyperosmolar state.

- Use the assorted calibration chip that accompanies each type of test strip when tests are applied. Used with single-use, auto-disabling lancing device.

- Test only whole blood samples with the assorted PLUSMED fasTTest DiagnoPro brand Blood Glucose Test Strips, Blood β-Ketone Test Strips and Blood Uric Acid Test Strips along with PLUSMED fasTTest DiagnoPro Multi-Monitoring Meter.

- For self-testers, consult your physician or healthcare professional before making any adjustments to your medication, diet or activity routines.

- Keep out of reach of children.

By following the instructions outlined in this User's Manual, you will be able to use your PLUSMED fasTTest DiagnoPro Multi-Monitoring System to monitor your blood glucose, β-Ketone and uric acid and better manage your healthcare.

Table of Contents

Getting Started

Before testing, read the instructions carefully and learn about all the components of your PLUSMED fasTTest DiagnoPro Multi-Monitoring System. Please note that some of the components may need to be purchased separately from your local distributor. Please check the list of contents on the outer box for details on which components are included with your purchase.

Meter

Test Strip*
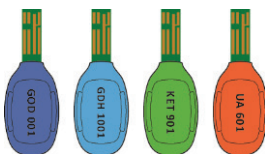
Calibration Chip*

Carrying Case

Control Solution*

Lancing Device

Lancets*

Note: "*" means these components need to be purchased separately and is not included in the Meter package.
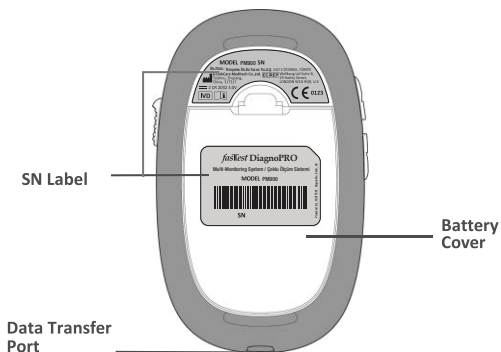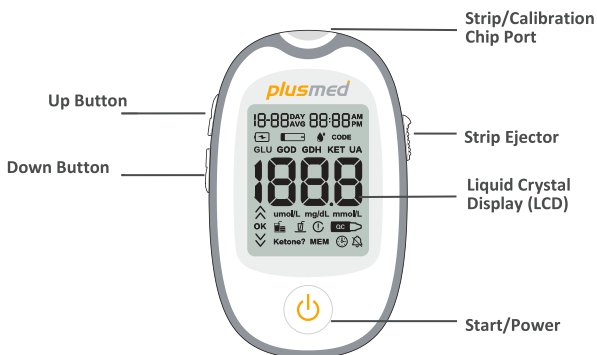
Components Descriptions

1. PLUSMED fasTTest DiagnoPro Multi-Monitoring Meter: Reads the test strips for blood glucose, β-Ketone, uric acid and displays each concentration.

2. Test Strips: Strips with a chemical reagent system used with the meter to measure glucose, β-Ketone or uric acid concentration in blood.

3. Calibration Chip: Automatically calibrates the meter with the type of test strips a patient wants to perform once inserted into the meter.

4. Lancing Device: Used with sterile lancets to prick the fingertip for blood sample collection. The packaged lancing device has multiple depth settings, allowing users to adjust the depth of the puncture and minimize discomfort. It can also eject the used lancets.

5. Sterile Lancets: Used with the lancing device to draw a blood sample. Sterile lancets are inserted into the lancing device with each blood draw and discarded after use.

6. Control Solution: Verifies the proper operation of the PLUSMED fasTTest DiagnoPro Multi-Monitoring System by checking the test strips and meter against a pre-calibrated control solution, which are available in the PLUSMED fasTTest DiagnoPro Multi-Monitoring System Control Solution package which is sold separately.

   Note: For Glucose and β-Ketone control solution, there are three levels with Level 1, Level 2 and Level 3. For Uric Acid, there are two levels with Level 1 and Level 2.

7. Carrying Case: Provides portability for testing wherever you go.

8. User's Manual: Provides detailed instructions on using the PLUSMED fasTTest DiagnoPro Multi-Monitoring System.

PLUSMED fasTTest DiagnoPro Multi-Monitoring Meter

The meter reads the test strips of blood glucose, β-Ketone and Uric Acid and displays each concentration. Please read diagrams below to become familiar with all the parts of your meter.

Strip/Calibration Chip Port

Up Button

Down Button

Strip Ejector

Liquid Crystal Display (LCD)

Start/Power

SN Label

Battery Cover

Data Transfer Port

Strip Port: Test strips are inserted into this area to perform a test / Coding the meter by inserting the calibration Chip.

Strip Ejector: Slide the ejector forward to discard the used test strip.

Liquid Crystal Display (LCD): Shows your test results, and helps you through the testing process.

Start/Power: Enter setting model and confirm the setting, when the meter is in PC and Memory mode, press Start/Power button, the meter will turn off.

**Up Button:** Selects meter settings and performs other menu selection functions.

Down Button: Recalls previous test results from the meter memory and performs other menu selection functions.

Battery Cover: Remove the battery cover to install two CR2032 coin cell batteries.

Data Transfer Port: Sends information to a computer via an optional data transfer cable to view, analyze and print stored data in the meter. The data transfer cable is available for order as an optional add-on.

Attention: Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing of blood samples and materials.

Meter Display
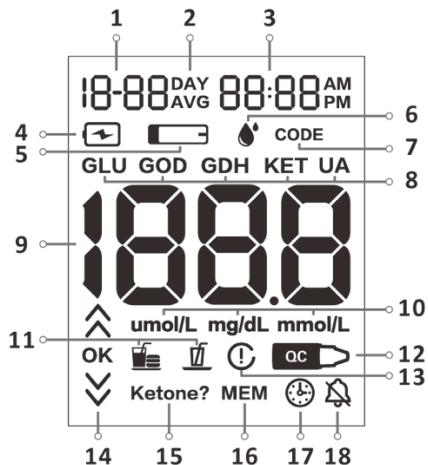
Number	Symbol	Indicator	Means
1	18-88	Date	Indicates the testing date in month/day format.
2	DAY AVG	MEM Average	Average glucose in 7, 14, 30, 60 and 90-days.
3	88:88 AM PM	Time	Indicates the time of 24H format or 12H format.
4	(battery icon)	Low Power Icon	Warns you when you should replace the battery.
5	(strip icon)	Strip Icon	Blood Drop / Strip Icon will appear before applying the sample and during the time of meter reminding. These two symbols appear at the same time.
6	(blood drop icon)	Blood Drop Icon	Blood Drop / Strip Icon will appear before applying the sample and during the time of meter reminding. These two symbols appear at the same time.

7	**CODE**	Code Icon	Indicates the test strip calibration code number.
8	**GLU GOD / GLU GDH or KET or UA**	Strip type or Test Parameter	Indicates different strip type or test parameter. GLU GOD / GLU GDH means the meter is currently performing the glucose test with strip of either GOD or GDH enzyme. KET means blood β-Ketone test, UA stands for blood uric acid test.
9	**1888**	Test Result Area	Indicates the test result and calibration code number.
10	**mg/dL** **mmol/L** **umol/L**	Measure-ment Unit	Measurement units differ from different test parameter. mg/dL and mmol/L for Glucose Units, mmol/L for Ketone, mg/dL and μmol/L for Uric Acid. *Note*：When glucose testing is performed, only one unit of measure will be displayed on your meter and it cannot be adjusted.
11		Before Meal Icon	Appears when before-meal test results are displayed.
		After Meal Icon	Appears when after-meal test results are displayed.
12	**QC**	QC Icon	Indicates a test result when running quality control.
13		Invalid Value Icon	Appears if mark the value is invalid, and also will be displayed together with control solution value.
14	⩘ **OK** ⩗	Glucose Target Range	Up Arrow Symbol appears when the blood glucose concentration is above the "Hyperglycemia" (high blood sugar level) target level that you have set. Down Arrow Symbol: Appears when the blood glucose concentration is below the "Hypoglycemia" (low blood sugar) target level that you have set.

15	Ketone?	Blood Ketone Reminder Symbol	Appears when the blood glucose concentration is above 16.7 mmol/L (300 mg/dl). This simply suggests that a β-Ketone test is recommended. Consult your healthcare professional about testing for β-Ketones. **_Note:_** This symbol does not mean that the system has detected β-Ketones. It recommends that a β-Ketone test should be taken.
16	**MEM**	MEM	Shows a test result stored in memory.
17		Test Remind Icon	This icon appears to remind you to test your blood glucose.
18		Sound Icon	This icon appears when the sound is turned off.

Meter Use and Precautions

- Wait for the Blood Drop / Strip Symbol to appear before applying the sample.

- The meter is pre-set to display depending on which unit of measure is standard in your country. Blood glucose concentration in either millimole per liter (mmol/L) or milligrams per deciliter (mg/dL), uric acid concentration in either milligrams per deciliter (mg/dL) or micromole per liter (μmol/L). This unit of measure cannot be adjusted.

- The meter will shut off automatically 2 minutes after inactivity.

- Do not get water or other liquids inside the meter.

- Keep the strip port area clean.

- Keep your meter dry and avoid exposing it to extreme temperatures or humidity. 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.

- Do not take the meter apart. Taking the meter apart will void the warranty.

- Keep the meter and all associated parts out of the reach of children.

  Note: Follow proper precautions and all local regulations when disposing of the meter and used battery.

All Systems Preventive Warnings with Regard to EMC:

- This instrument is tested for immunity to electrostatic discharge as specified in IEC 61000-4-2. However, 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.

- This instrument complies with the emission and immunity requirements described in EN61326-1 and EN61326-2-6. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with proper operation of the meter.

- For professional use, the electromagnetic environment should be evaluated prior to operation of this device.

PLUSMED fasTTest DiagnoPro GLU GOD/GLU GDH/KET/UA Test Strips

The PLUSMED fasTTest DiagnoPro GLU GOD/GLU GDH/KET/UA Test Strips are thin strips with a chemical reagent which works with the PLUSMED fasTTest DiagnoPro Multi-Monitoring Meter to measure the glucose, β-Ketone or uric acid concentration in whole blood respectively. After the strip is inserted into the meter, blood is applied to the sample tip of the test strip. The blood is then automatically absorbed into the reaction cell where the reaction takes place. A transient electrical current is formed during the reaction and the blood glucose, β-Ketone/uric acid concentration is calculated based on the electrical current detected by the meter. The result is shown on the meter display. The meter is calibrated to display plasma equivalent results.
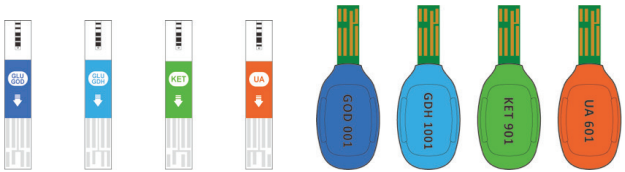
Example of a blood glucose test strip using glucose oxidase (GOD):

Sampling Tip   **Direction Arrow**

Apply blood or control solution area   Insert strips following the arrow direction


Check Window   **Contact Bars**

Check to confirm that a sufficient   Insert this end of the test strip
sample has been applied.   into the meter until it stops.

IMPORTANT: Apply the sample only to the sample tip of the test strip. Do not apply blood or control solution to the top of the test strip as this may result in an inaccurate reading.

Hold the blood drop to the sample tip of the test strip until the check window is completely full and until the meter begins to count down. If you applied blood but do not see the starting of the count down, you may reapply a second drop of blood within 3 seconds. If the check window does not fill and the meter starts to countdown, then do not add more blood to the test strip. If you do, then you may get an E-5 message or an inaccurate test result. In this case, if the meter begins to countdown and the check window does not fill, discard the strip and begin the test again with a new test strip.
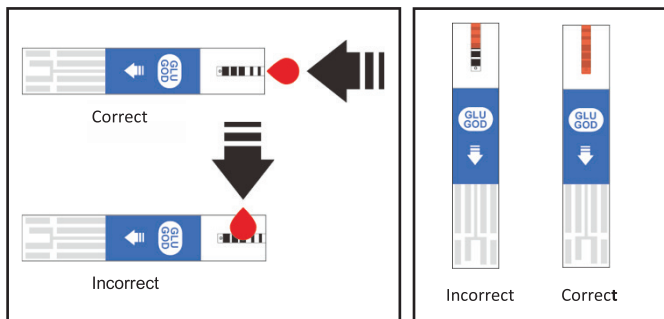
Code Number

Each package of test strips is printed with a code number (CODE), lot number (LOT), unopened expiration date ( ) and control range. Please make sure that the calibration code number printed on the package of each test strip matches with the code inside of the package.

Storage and Handling

Please review the following storage and handling instructions:

- Store test strips in a cool, dry place, 2 - 35°C (36 - 95°F) for glucose strips, 2 - 30°C (36 - 86°F) for uric acid strips. Store them away from heat and direct sunlight.

- Do not freeze or refrigerate.

- Do not store or use test strips in a humid place such as a bathroom.

- Do not store the meter, the test strips or control solution near bleach or cleaners that contain bleach.

- The test strip should be used immediately after removing it from the container.

- Repeated insertion and removal of a test strip into the meter strip port may result in reading errors.

- Do not use your test strips past the unopened expiration date printed on the label. Using test strips past the unopened expiration date may produce incorrect test results.

  Note: The expiration date is printed in Year-Month format. 2018-01 means January, 2018.

Special Instructions for Test strip in the Vial

- Test strips must be stored in the original vial with the cap tightly closed. This keeps them in good working condition.

- Do not transfer test strips to a new vial or any other container.

- Close tightly the cap on the test strip vial immediately after removing a test strip.

- A new vial of test strips may be used for 6 months after being first opened. Write the opened expiration date on the vial label after opening. Discard the vial 6 months after you first open it. Usage after this period may result in inaccurate readings.

  Note: Blood Uric Acid test strips may only be used for 3 months after being first opened.

Special Instructions for Test Strip in the Foil Pouch

- Tear the pouch carefully from the tear gap. Avoid damaging or bending the test strip.
- Use the test strip immediately after removing it from the pouch.

Test Strip Precautions

- For *in vitro* diagnostic use. Test strips are to be used only outside the body for testing purposes.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- Keep the test strips vial or the foil pouch away from children and animals.
- Consult your physician or healthcare professional before making any changes in your treatment plan based on your test results.

See the test strip insert for more details.

PLUSMED fasTTest DiagnoPro GLU/KET/UA Control Solution

The PLUSMED fasTTest DiagnoPro GLU/KET/UA Control Solution contains a known concentration of glucose, β-Ketone and uric acid respectively. It is used to confirm that your PLUSMED fasTTest DiagnoPro Multi-Monitoring meter and test strips are working together properly and you are performing the test correctly. It is important to run a quality control test regularly to make sure you are getting correct results.

You should run a quality control test:

- Before you first use your meter, to familiarize yourself with its operation.
- Before using a new box of test strips.
- When you suspect that the meter or test strips are not working properly.
- When you suspect that your test results are inaccurate, or if they are inconsistent with how you feel.
- When you suspect your meter is damaged.
- After cleaning your meter.
- At least once a week.

Refer to the Section **Quality Control Test** for instructions on running a quality control test.

Storage and Handling

Please review the following storage and handling instructions:

- Store the glucose and β-Ketone control solution at 2 - 35°C (36 - 95°F), and store uric acid control solution at 2 - 30°C (36 - 86°F).

- Do not refrigerate or freeze.

- If the control solution is cold, do not use until it has warmed to room temperature.

- Use before the unopened expiration date that is shown on the bottle.

  Note: The expiration date is printed in Year-Month format. 2018-01 means January, 2018.

- Each bottle of control solution can be used for 6 months after you first open it. Record the opened and the resulting expiration dates on the bottle label.

  Note: Uric acid control solution may only be used for 3 months after being first opened.

Control Solution Precautions

- For *in vitr*o diagnostic use. The control solution is for testing only outside the body. Do not swallow or inject.

- Shake well before using.

- Glucose and β-Ketone control solution tests are designed to be accurate only when tested between 5 and 45°C (41 - 113°F), while uric acid control solution tests are safe to perform between 10 and 40°C (50 - 104°F).

- The control ranges shown on the test strip vial (or on the foil pouch) are not recommended ranges for your blood glucose/ β-Ketone /uric acid level. Your personal blood glucose/ β-Ketone / uric acid target ranges should be determined by your healthcare professional.

- Do not touch the test strip with the tip of the control solution bottle directly.

- Use only the same brand of control solution that was provided with your kit.

See the control solution insert for more details.

Installing Batteries

The batteries may not be preinstalled in the meter. Two CR2032 3.0V coin cell batteries are required. Please find the batteries in your carrying case and install them according to the following steps:

1. Turn over the meter and slide the battery cover in the direction of the arrow to open it.
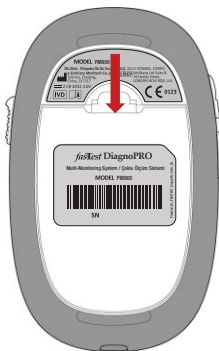
2. Place two fresh CR 2032 3.0V coin cell batteries. Make sure they are aligned with the plus (+) side facing up in the battery carrier.
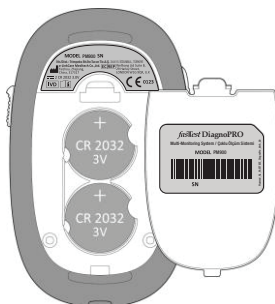
3. Close the battery cover and make sure that it snaps shut.

Meter Setup Before Testing

Before using your meter for the first time, you will need to adjust the settings that are listed in detail below:

1. **Meter Setup Mode:** Press the Power button for 2 seconds. The meter will automatically enter the setup mode for the first time by any method. Please double check the battery level. Replacing with new batteries may also enable this mode.

2. **Clock:** Set the clock to 12 or 24-hour mode. Press the Up or Down button to switch between the two settings, then press the Power button to save your choice and then start setting the year, month and date.

   Note: The clock needs to be reset after replacing the battery.

3. **Date:** The year will appear at the top of the display. Press the Up or Down button to select the proper year. Once you have selected the correct year, press the Power button to save your choice and start setting the month. Press the Up or Down button to select the proper month. Then press the Power button to save your choice and start setting the date. Press the Up or Down button to select the proper date. Then press the Power button to save your choice and start setting the time.

| Year	Month	Date
20 17	9-	9-08
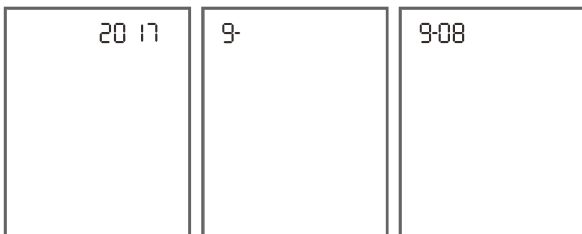
4. **Time:** The hour will appear at the top of the display. Adjust the hour with the Up or Down button until the correct hour is displayed. Press the Power button to save your choice and set the minutes. Press the Up or Down button to change to the correct minute. Pressing and holding can help with faster time adjustment. Press the Power button to save your choice and move to set the audio.

Hours	Minutes
9-08 16:	9-08 16:08
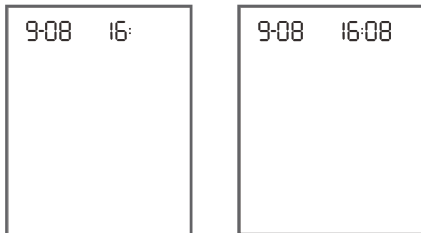
5. **Audio Feature:** The meter comes with the meter audio feature enabled. Press Up or Down button to switch between ON and OFF. The meter will give one short beep when it is turned on, after sample detection and when the result is ready. The meter will sound three short beeps to indicate a warning when an error has occurred. Please check the error number on the display to confirm what kind of error has occurred.

OR
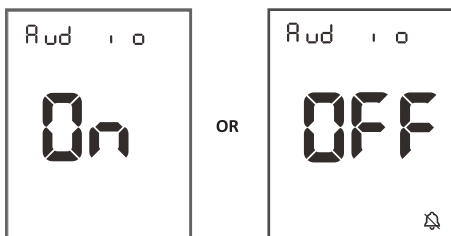
6. **Meal Marker:** The meter comes with the meal marker feature disabled. The meter allows the user to enable or disable the meal marker option. The words "On" or "Off" will be displayed on the large center segments of the display and the before meal icon together with the after-meal icon will be displayed as shown below.


OR
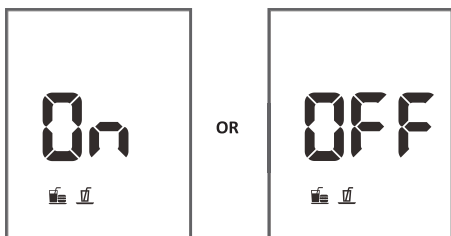
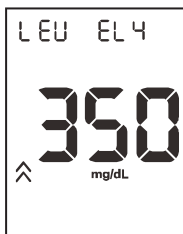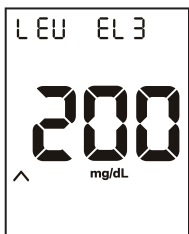Press the Up or Down button to switch between turning the meal marker "On" and "Off". Press the Power button to confirm your selection.

7. **Ketone Indicator:** The meter comes with the ketone indicator feature disabled. Press the Up or Down button to switch between turning the ketone indicator "On" and "Off". Press the Power button to confirm your selection.
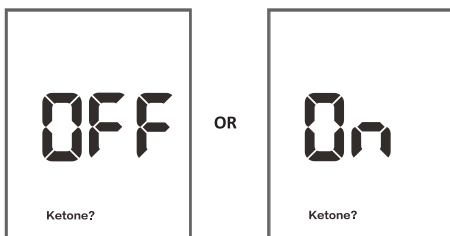
When the ketone indicator is enabled, if the test result is higher than 16.7 mmol/L (300 mg/dl) the symbol of "ketone?" will appear on the display.

8. **Range Indicator:** The meter comes with the Range indicator feature disabled. Press the Up or Down button to turn the Range indicator "On" or "Off". Press the Power button to confirm your selection. When the Range indicator is "Off", pressing the Power button (to select) will lead you to the Alarm set up.
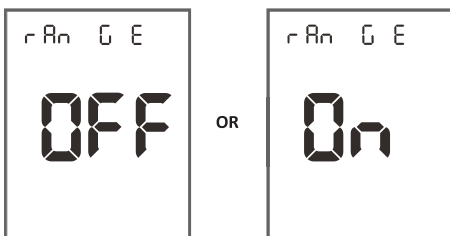

When the Range indicator is "On", pressing the Power button will lead you to level set up. There are 4 levels of ranges you can set up, it is strongly recommended to consult with your healthcare specialist to select the ranges. At the level set up, press the Up or Down button to adjust the level then press the Power button to go to the Alarm set up mode.

LEVEL1   50 mg/dL   ⌄⌄

LEVEL2   70 mg/dL   ⌄

LEVEL3   200 mg/dL   ⌃
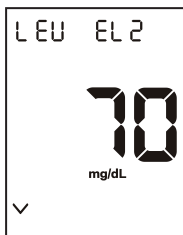
LEVEL4   350 mg/dL   ⌃⌃

Note: The meter default setup level is Level 1 50 mg/dL, Level 2 70 mg/dL, Level 3 200 mg/dL, Level 4 350 mg/dL for diabetes. Please Consult your diabetes healthcare professional before determining what your hyper or hypo blood glucose levels are.

9. **Test Reminder:** Test reminder is a useful way to remind you when to test. You can set 1 to 5 reminders per day. Your meter is preset with the test reminder disabled. You must turn it on to use this feature.

- Press the Up or Down button to switch between turning the first Test Reminder "On" and "Off". Press the Power button to confirm your selection. When the Test Reminder is "Off", pressing the Power button will go to the setup of the second Test Reminder. When the Test Reminder is "On", pressing the Power button will lead you to the setup of the time for the first Test Reminder. Press the Up or Down button to adjust the first Test Reminder time. (Time is adjusted by every 5 minutes.) Press the Power button to confirm the first Test Reminder time and then go to the second Test Reminder set up.

- When the Test Reminder is "Off" during the second Test Reminder set up, pressing the Power button will lead you to the setup of the third Test Reminder. When the

Test Reminder is "On", pressing the Power button will lead you to the set-up of the time for the second Test Reminder.
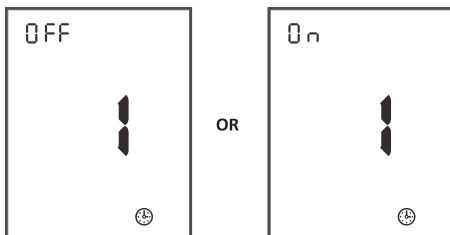

- Press the Up or Down button to adjust the second Test Reminder time. (Time is adjusted by every 5 minutes.) Press the Power button to confirm the second Test Reminder time and then go to the third Test Reminder set up.
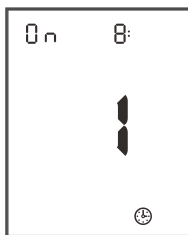

- Repeat the same set up procedure for Test Reminder 3, 4 and 5.

- After finishing the fifth Test Reminder set up, it will then end the setup mode and the meter will power off.

If one or more test reminders have been set, the reminder symbol will always appear on the LCD screen when the meter is turned on. The display sample is shown below.
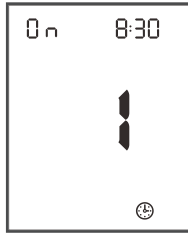
The meter beeps 10 seconds at the time you set. During the beeping, inserting a test strip or pressing the power button will turn off the beep. This function will still work with the Audio feature turned off.

When the meter beeps at the time set by the Test Reminder feature, the date, time and strip symbol will be displayed. And the strip symbol will flash. The display sample is shown below.
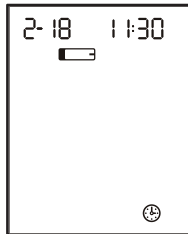
Coding the meter

It is necessary and important to calibrate the system every time you open a new kit box. To do that, simply insert the code chip to the strip port of the meter for corresponding tests every time you change to a new box of test strips. You can easily find a code chip in your strip box.

With your meter turned off, insert the corresponding code chip into the strip port of the meter. It should easily snap into place. Once you have coded the meter, you can take out the code chip and start testing blood glucose, blood β-Ketone and blood uric acid accordingly.
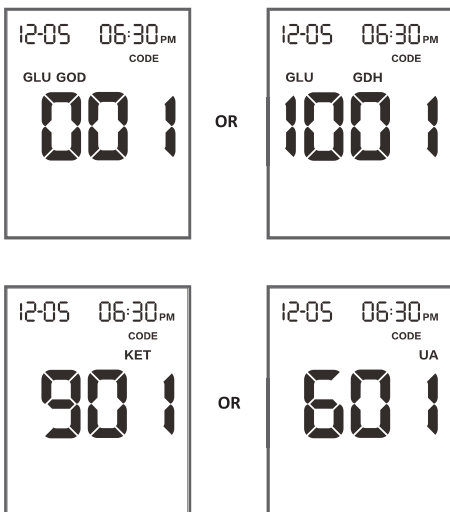
Example of a blood glucose test strip using glucose oxidase (GOD):
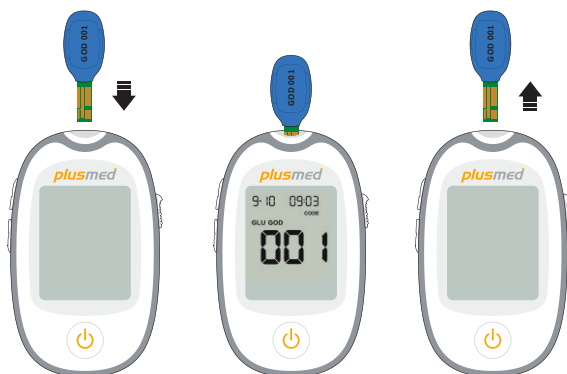
Note:

Each code chip is printed with letters representing the strip type and code number. "GOD" indicates the code chip is for the blood glucose test strip using glucose oxidase, "GDH" indicates the code chip is for the blood glucose test strip using glucose dehydrogenase FAD-dependent, "KET" indicates the code chip is for the blood β-Ketone test strip, and "UA" indicates the code chip is for the blood uric acid test strip. For example, "GOD 001" indicates that the code chip is for the blood glucose test strip using glucose oxidase, code number is "001".

The code number for each type of test strip is different. The blood glucose test strip using glucose oxidase (GLU GOD) is with a 3-digit code number, the blood glucose test strip using glucose dehydrogenase FAD-dependent (GLU GDH) starts from "1000" with a 4-digit code number, the blood β-Ketone test strip is with a 3-digit code number, and the blood uric acid test strip is with a 3-digit code number.

12-05 06:30PM
CODE
GLU GOD
001

OR

12-05 06:30PM
CODE
GLU GDH
1001

12-05 06:30PM
CODE
KET
901

OR

12-05 06:30PM
CODE
UA
601

The meter will automatically log in the last coding information for each parameter, if you forget to code the meter in this parameter, the meter will display "---" when you insert the strip into the strip port of the meter.

9-10 09:03
GLU GOD
— — —

OR

9-06 11:19AM
KET
— — —
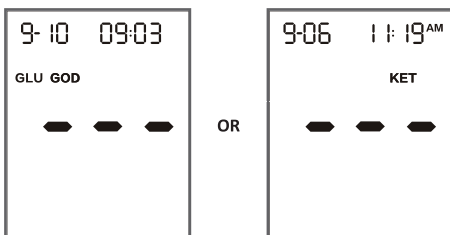
If the calibration chip is damaged or incorrect, the meter will report E10 or E11 directly.

Note: Once the meter is coded, it's not required to code again when switching among blood glucose & β-Ketone & uric acid. The meter will automatically detect the type of test when strip is inserted.

E 10 OR E 11

Performing a Quality Control Test

The quality control test confirms that the test strips and meter are working together properly, and that you are performing the test correctly. It is important to perform this test:

- At the first time of use.
- Before using a new lot of test strips.
- When you suspect that the meter or test strips are not working properly.
- When you suspect that your test results are inaccurate, or if they are inconsistent with how you feel.
- When you suspect your meter is damaged.
- After cleaning your meter.
- At least once a week.

Example of a blood glucose test strip using glucose oxidase (GOD)：

1. Insert a test strip into the strip port, contact bars end first and facing up, to turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.

2. Check the display to confirm that all of the display segments are turned on. Next, a dash will move across the display.

| Turn On | Meter Self-check | Not Ready |
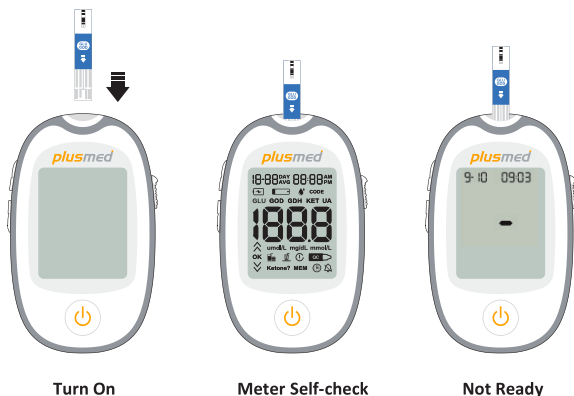
3. The display will show the date and time. The strip icon with the blood sample icon will blink to indicate that the test strip is inserted correctly.

*Note*: If the test strip has been inserted incorrectly, the meter will not turn on.

4. Compare the strip type and code number on the meter display with the strip vial label (or strip foil pouch) which being tested, and make sure that they match. If the code number on the display does not match the code number on the test strip vial (or strip foil pouch), code the meter again by inserting the code chip that came with the box of test strips into the meter.

5. Shake the control solution bottle well, then squeeze it gently and discard the first drop. If the tip clogs, tap the tip gently on a clean, hard surface. Then shake again and use. Squeeze out a second small drop on a clean nonabsorbent surface. Touch the sample tip of the test strip to the control solution drop. If the audio option is turned on, the meter will beep to indicate a sufficient sample has been applied.

Notes:

- PLUSMED fasTTest DiagnoPro Blood Glucose Control Solution is a blue colored liquid with three levels (Level 1, Level 2, Level 3), and it's used both for Glucose GOD and GDH-FAD test strips.

- PLUSMED fasTTest DiagnoPro Blood Ketone Control Solution is a red colored liquid with three levels (Level 1, Level 2, Level 3), and PLUSMED fasTTest DiagnoPro Uric Acid Control Solution is red colored with two levels (Level 1 & Level 2).

- Do not apply control solution to the test strip directly from the bottle.

- If you applied the control solution sample but do not see the starting of the count down, you may reapply a second drop within 3 seconds.

6. Once a sufficient sample has been applied, the meter display will count down (4 for glucose, 4 for Ketone, and 14 for UA) to 1 and then the result and a control solution symbol will be displayed on the screen. The control solution test results should be within the control range printed on the test strip vial (or on the foil pouch). This means that your blood glucose monitoring system is working properly and that you are performing the procedure correctly.
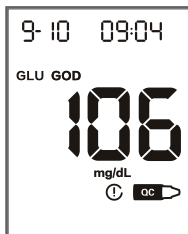
Note: Glucose test results are displayed either in mmol/L or mg/dL depending on the unit of measure that is commonly used in your country, while Ketone test results are displayed as mmol/L, and Uric Acid test results are displayed as μmol/L or mg/dL depending on the unit of measure that is commonly used in your country.

Note: The control solution range is the expected range for the control solution results. It is not a recommended range for a blood glucose level.

The display should also show a pound sign (�) indicating the test is a control solution test.

7.   Slide the strip ejector forward to discard the used test strip.

If the result falls outside the indicated control range:

- Confirm you are matching the correct range. Control Solution 1 results should be matched to the Level 1 range printed on the test strip vial (or on the foil pouch).

- Check the expiration date of the test strip and control solution. Make sure that the test strip vial and control solution bottle have not been opened for more than 6 months (3 months for blood uric acid test strip and uric acid control solution). Discard any test strips or control solution that has expired.

- Confirm the temperature in which you are testing is between 5 and 45°C (41 - 113°F). Note that uric acid control solution test only can be performed between 10 and 40 °C (50 - 104°F).

- Make sure that the test strip vial and control solution bottle have been tightly capped.

- Confirm that you are using the same brand of control solution that was provided with your kit.

- Make sure that you follow the test procedure correctly.

After checking all of the conditions listed above, repeat the quality control test with a new test strip. If your results still fall outside of the control range shown on the test strip vial (or on the foil pouch), your meter may be defective. Contact your local distributor for help.

Three levels of Control Solution are available labeled Control Solution 1, Control Solution 2 and Control Solution 3 for glucose and ketone, and two levels for uric acid. Ketone and uric acid control solutions are for professional use only. Glucose Control Solution 2 can be sufficient for most of glucose self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 1 or level 3 test. The ranges for Level 1, Level 2 and Level 3 are displayed on the test strip vial (or on the foil pouch). Simply repeat step 4 through 6, using Control Solution 1 or Control Solution 3.

To confirm your results, Control Solution 1 tests should fall within the Level 1 range, Control Solution 2 tests should fall within the Level 2 range and Control Solution 3 tests should fall within the Level 3 range. If the control solution test results do not fall within their respective ranges, DO NOT use the system to test blood, as the system may not be working properly. If you cannot fix the problem, please contact your local distributor for help.

Please contact your local distributor for information on ordering the PLUSMED fasTTest DiagnoPro Control Solution kit. The kit contains Control Solution 1, Control Solution 2 and Control Solution 3 for glucose and ketone, and Control Solution 1 and Control Solution 2 for Uric Acid.

Testing Your Blood

The following steps will show how to use the meter, test strips, lancing device and sterile lancets together to measure your blood Glucose/Ketone/Uric Acid concentration.

Step 1 – Getting a Drop of Blood

The PLUSMED fasTTest DiagnoPro Multi-Monitoring System requires a very small drop of blood which may be obtained from the fingertip for glucose, or ketone, or uric acid test only. Before testing, choose a clean, dry work surface. Familiarize yourself with the procedure and make sure you have all the items needed to obtain a drop of blood.

IMPORTANT: Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water 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.
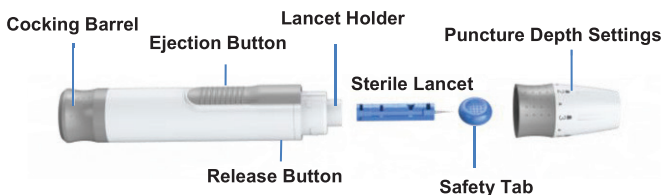
Fingertip Testing

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 lancet holder and push it until the lancet comes to a complete stop in the lancing device.
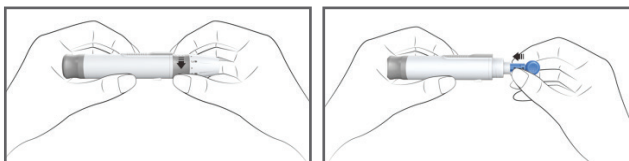
2. Hold the lancet firmly in the lancing device and twist the safety tab of the lancet until it loosens. Then pull the safety tab off the lancet. Save the safety tab for lancet disposal.

3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed

needle. Make sure the cover is fully sealed on the lancing device.
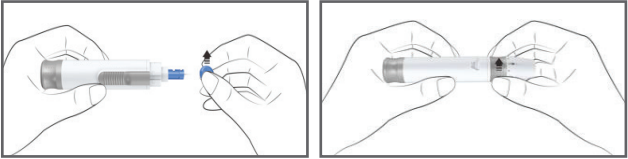
4. Adjust the puncture depth by rotating the lancing device cover. There is a total of 11 puncture depth settings. To reduce the discomfort, use the lowest setting that still produces an adequate drop of blood.


OR
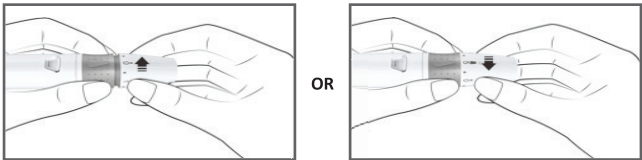
Adjustments:

0 - 1.5   for delicate skin

2 - 3.5   for normal skin

4 - 5   for calloused or thick skin

Note: Increased pressure of the lancing device against the finger will also increase the puncture depth.

5. Pull the cocking barrel back to set the lancing device. You may hear a click, while the release button changes to orange to indicate the lancing device is now loaded and ready for obtaining a drop of blood.
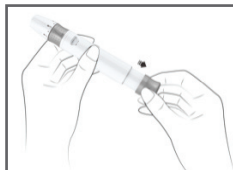
6. Prior to testing, clean your hands with an alcohol wipe or wash your hands with soap. Use warm water to increase blood flow in your fingers if necessary. Dry your hands thoroughly. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.
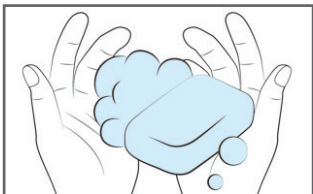
7. Hold the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You may hear a click as the lancing device activates. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the drop of blood.

For the greatest reduction in pain, lance on the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make your fingers sore and callused.
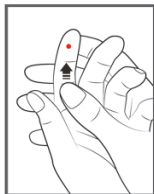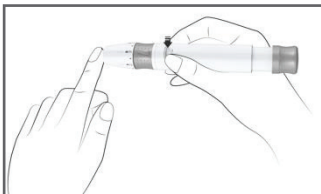
Disposal of the Lancet

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

2. Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to discard the used lancet. Place the lancing device cover back on the lancing device.


Lancet Precautions

- Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.

- Do not use the lancet if the needle is bent.

- Use caution whenever the lancet needle is exposed.

- Never share lancets or the lancing device with other people.

- In order to reduce the risk of infection from prior use of the instrument, always use a new, sterile lancet. Do not reuse lancets.

- Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt or debris.

Step 2 – Testing Your Blood

Note: **Insertion of a new test strip at any time, except while in the data transfer mode will cause the meter to automatically enter the test mode.**

Testing your Blood Glucose

1. Insert a test strip into the strip port, contact bars end first and facing up, to turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.

2. Check the display to confirm that all the display segments turn on with no missing components. The display will then show only the date and time, with a dash moving across the display. Check the display to ensure no inappropriate segments or icons are permanently turned on.

| **Turn On** | **Meter Self-check** | **Not Ready** |
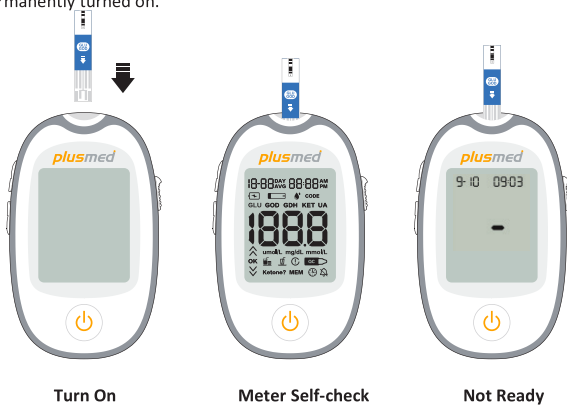
3. Following this display check, the system will enter the test mode. The display will show the date and time as well as the strip icon, and the blood sample icon starts blinking to indicate that the test strip is inserted correctly and a drop of blood can be added. If the test strip has been inserted incorrectly, the meter will not turn on. The meter is ready for testing when the blinking blood drop and strip symbol appears. At this time, a blood drop can be added.
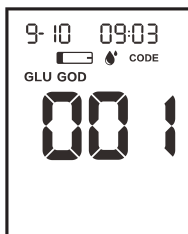
4. Compare the strip type and code number on the meter display with the strip vial label (or strip foil pouch) which is being tested, and make sure that they match. If the code number on the display does not match the code number on the test strip vial (or strip foil pouch), code the meter again by inserting the code chip that came with the box of test strips into the meters.
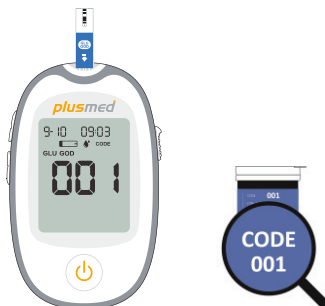

5. Touch the blood sample to the sample tip at the end of the test strip. If the audio option is turned on, the meter will beep to indicate the sample is sufficient and the measurement has started. If you applied a drop of blood, but do not see the starting of the countdown, you may reapply a second drop of blood within 3 seconds.
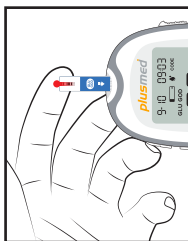
DO NOT:

- Apply the sample to the front or back of the test strip.

- Smear the blood drop onto the test strip.

- Press your finger against the test strip.

6. The meter will count down from 4 to 1 and then display the measurement's results. The meter will also beep to indicate that measurement is completed. Then your blood glucose level will display on the screen. The measurement's unit, date, and time of the test will also be displayed.
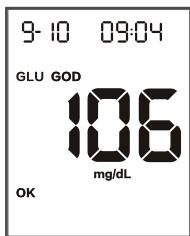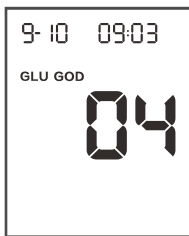
Note: Blood Glucose results are automatically stored in the memory.

7. If a result is marked by accident, press the POWER button to unmark the result. Press the POWER button to mark the invalid result, A pound sign (⏻) will appear on the display to show that the result will not be included when calculating the 7, 14, 30, 60 and 90-day averages. The pound sign (⏻) will also be displayed when reviewing the results stored in memory. After marking the invalid result, run the test again with a new test strip.
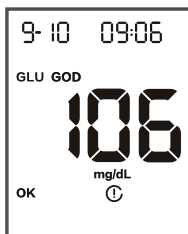
When the above display is shown on screen, Press the POWER button again to disable all markers for the result.

If an invalid result is marked, run the test again with a new test strip.

8. After inspection, record valid results in your logbook with the date and time, and compare them to the target goals set by your diabetes healthcare professional. Refer to Suggested Test Times and Target Goals for more details on your target blood glucose concentration goals.

9. Slide the strip ejector forward to discard the used test strip.

    Note: Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing of blood samples and materials.
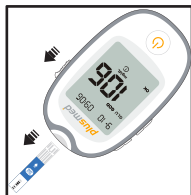

Before meal or after meal remark:

When the meal marker feature is turned on and a test result is displayed, mark the result as "before meal", or "after meal".

1. Press the POWER buttons one time to display the "before meal marker" Icon, indicating the result was taken before a meal.
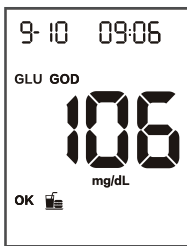
2. Press the POWER button again to display the "after meal marker" symbol, indicating the result was taken after a meal.
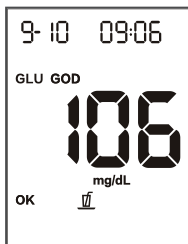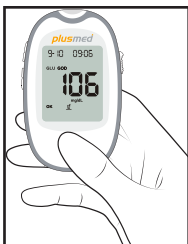
Glucose Range Indicator Message

The meter comes with the Range indicator feature disabled. Please refer to **Meter Setup Before Testing** section to find out how to turn the range indicator function on.

When the Glucose Range indicator is "On", pressing the Power button will lead you to level set up. There are 4 levels of ranges you can set up. We strongly recommed users to consult your diabetes professional to select your glucose ranges.

Note: The glucose range indicator feature is only available when glucose testing is applied.

With the glucose range indicator feature turned on, when the glucose result is displayed, an arrow message may also appear depending on system configuration, notifying you if the result exceeds the specified limit values. Additionally an arrow "∧" or "∨" may appear next to the result to indiciate that a result is out of range.

Double Down arrow means your glucose value is below the critical lower concentration. (Configurable range from 30 mg/dL to 60 mg/dL or equivalent to 1.67 mmol/L to 3.33 mmol/L)

One Down arrow means your glucose value is below your target blood glucose concentration. (Configurable range should be above critical lower range and up to 120 mg/dL or equivalent to 6.67 mmol/L)
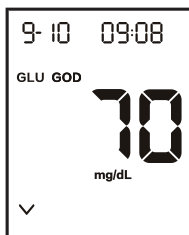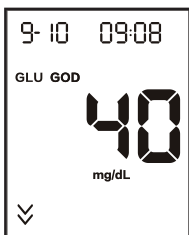

OK means your glucose value is within safe range.

One Up arrow means your value is above your target blood glucose concentration. (Configurable range from 121 mg/dL to 230 mg/dL or equivalent to 6.7 mmol/L to 12.8 mmol/L)

Two Up arrows mean your glucose value is above the critical hyperglycemic concentration. (Configurable range should be above normal hyperglycemic range and up to 380 mg/dL or equivalent to 21.1 mmol/L)
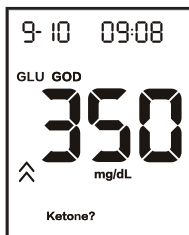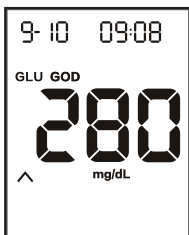
*Note***:** These limit values define ranges that can either be configured individually by the system administrator in line with facility guidelines or are the (technical) limits of the system. Please consult your diabetes healthcare professional before determining what your hyper or hypo blood glucose levels are.

"HI" and "LO" Messages

The meter can accurately measure blood glucose concentrations between 0.6 to 33.3 mmol/L (10 to 600 mg/dl). "HI" and "LO" messages indicate if results are outside of this range.

If "HI" appears on the display, the measured concentration value is above 33.3 mmol/L (600 mg/dl). The test should be retaken to ensure that no mistake was made in the procedure. If you are certain the meter is functioning properly and no mistakes were made in the procedure, and your blood glucose is still consistently measured as "HI", it indicates severe hyperglycemia (high blood glucose). You should contact your healthcare professional immediately.

If "LO" appears on the display, the measured concentration value is below 0.6 mmol/L (10 mg/dl). The test should be retaken to ensure that no mistake was made in the procedure. If you are certain the meter is functioning properly and no mistakes were made in the procedure, and your blood glucose is still consistently measured as "LO", it may indicate severe hypoglycemia (low blood glucose). You should treat yourself for hypoglycemia immediately as recommended by your healthcare professional.
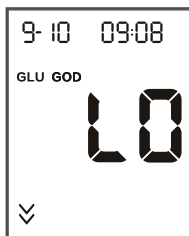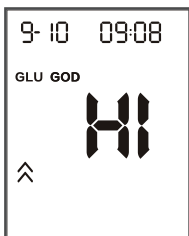
"Ketone?" Message

If "Ketone?" appears on the display, the measured concentration value is above 16.7 mmol/L (300 mg/dL). This simply suggests that a β-Ketone test is recommended. Consult your healthcare professional about testing for β-Ketones.
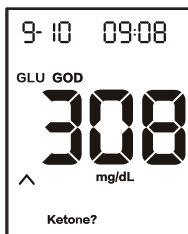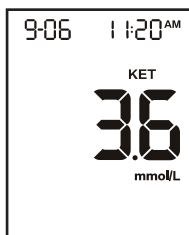
Testing your Blood Ketone

1. With your meter turned off, insert the Blood Ketone code chip into the strip port of the meter. It should easily snap into place. Once the code chip is inserted into the meter, the meter will automatically turn on, and you should see KET on the screen with the code number. Please make sure that the number displayed on the screen should match with the number on the vial or foil pouch of strips with which it was packaged. If the code number on the code chip displayed on the meter does not match the code number on the test strip vial label or on the individual strip pouch an erroneous result can be obtained. Contact the local distributor to correct the problem.

2. Now you are ready for a ketone test. Insert a ketone test strip into the strip port, contact bars end first and facing up, to turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.

3. Check the display to confirm that all the display segments turn on with no missing components. The display will then show only the date and time, with a dash moving across the display. Check the display to ensure no inappropriate segments or icons are permanently turned on.

4. Following this display check, the system will enter the test mode. The display will show the date and time and the strip icon with the blood sample icon blinking to indicate that the test strip is inserted correctly and a drop of blood can be added. If the test strip has been inserted incorrectly, the meter will not turn on. The meter is ready for testing when the blinking blood drop and strip symbol appears. At this time a blood drop can be added.

5. Compare the strip type and code number on the meter display with the strip vial label (or strip foil pouch) which is being tested, and make sure that they match. If the code number on the display does not match the code number on the test strip vial (or strip foil pouch), code the meter again by inserting the code chip that came with the box of test strips into the meter.

6. Touch the blood sample to the sample tip at the end of the test strip. If the audio option is turned on, the meter will beep to indicate the sample is sufficient and the meter starts to count down from 4 to 1. If you applied a drop of blood, but do not see the starting of the count down, you may reapply a second drop of blood within 3 seconds.

7. After inspection, record valid results in your logbook with the date and time, and compare them to the target goals set by your diabetes healthcare professional. Refer to **Suggested Testing Times and Target Goals** for more details on your target blood β-Ketone concentration goals.

8. Slide the strip ejector forward to discard the used test strip.

Testing your Uric Acid

1. With your meter turned off, insert the Uric Acid code chip into the strip port of the meter. It should easily snap into place. Once the code chip is inserted into the meter, the meter will automatically turn on, and you should see UA on the screen with the code number. Please make sure that the number displayed on the screen matches with the number on the vial or foil pouch of strips with which it was packaged. If the code number on the code chip displayed on the meter does not match the code number on the test strip vial label or on the individual strip pouch, an erroneous result can be obtained. Contact the local distributor to correct the problem.

2. Now you are ready for Uric Acid test. Insert a Uric Acid test strip into the strip port, contact bars end first and facing up, to turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.

3. Check the display to confirm that all the display segments turn on with no missing components. The display will then show only the date and time, with a dash moving across the display. Check the display to ensure no inappropriate segments or icons are permanently turned on.

4. Compare the strip type and code number on the meter display with the strip vial label (or strip foil pouch) which is being tested, and make sure that they match. If the code number on the display does not match the code number on the test strip vial (or strip foil pouch), code the meter again by inserting the code chip that came with the box of test strips into the meter.

5. Following this display check, the system will enter the test mode. The display will show the date and time and the strip icon with the blood sample icon blinking to indicate that the test strip is inserted correctly and a drop of blood can be added. If the test strip has been inserted incorrectly, the meter will not turn on. The meter is ready for testing when the blinking blood drop and strip symbol appears. At this time, a blood drop can be added.

6. Touch the blood sample to the sample tip at the end of the test strip. If the audio option is turned on, the meter will beep to indicate the sample is sufficient and the measurement has started. If you applied a drop of blood, but do not see the starting of the count down from 14, you may reapply a second drop of blood within 3 seconds.
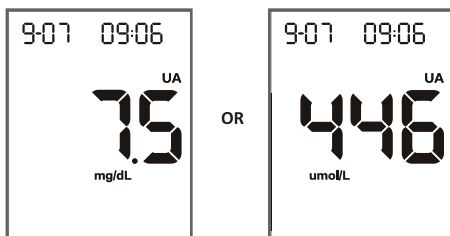
Note: The meter is preset to either micromoles per liter (μmol/L) or milligrams per deciliter (mg/dL) depending on the standard of your country, which you are unable to adjust by yourself.

7. After inspection, record valid results in your logbook with the date and time, and compare them to the target goals set by your diabetes healthcare professional. Refer to Suggested Testing Times and Target Goals on page 51 for more details on your target blood glucose concentration goals.

8.   Slide the strip ejector forward to discard the used test strip.
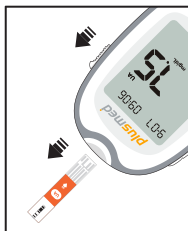
Recall the Meter Memory

The meter automatically stores up to 500 test records for Glucose, 100 for Ketone and Uric Acid each. Each record includes the test result, date and time. The oldest record will be erased to make room for a new one if memory reaches its limit.

The meter will also calculate the average values of glucose records from the last 7, 14, 30, 60 and 90 days.

Viewing Stored Records

To view stored records:

1. Press the Down button to turn the meter on and enter memory mode. The word "SEL" together with "MEM" will appear on the display. You can simply access stored records for glucose, ketone or uric acid by pressing the Down button. Once you have chosen the stored record, press the Up button to confirm.
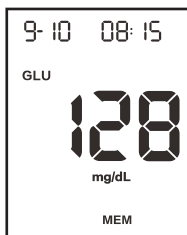
2. If you are using the meter for the very first time, the meter display will show three dashed lines (---), the word "MEM" and the unit of measure. This shows that no data has been stored in memory.
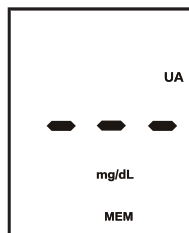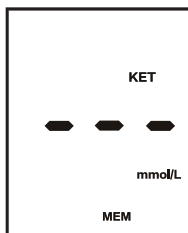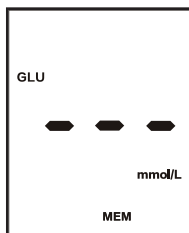
3. The date and time will be displayed together with the results stored in memory.

4. Press the Down button again to review the memory. The first result showed on the screen is the latest result that you have taken. Press the Down button to go through the stored records.

   Press the Power button to view the 7 days data averages in glucose memory mode. The words "7 DAY AVG" will appear on the top of screen. Press the Down button in order to view data average for 14 days, 30 days, 60 days and 90 days respectively.

   Press the Down button again to view average measurements data BEFORE meals and AFTER meals for the last 7,14,30,60 and 90 days. The meal marker symbol will appear on the screen respectively.

   Note: If you do not wish to view your average measurements, you can press the Power button again to turn off the display.

5. While in data average mode:

   - If the meal marker feature is off, press the Down button to switch between the general 7, 14, 30, 60 and 90-day averages.

   - If the meal marker feature is on, press the Down button to switch between the general 7, 14, 30, 60 and 90-day averages. The meter will calculate the average that you selected. The number of records used in the DAY AVG will also appear in the display.

   Note: All blood glucose results are included in the general 7, 14, 30, 60 and 90-day averages.
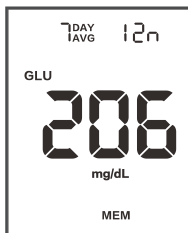
6. If there are fewer than 7, 14, 30, 60 and 90-days in memory, all the readings without the pound (⏻) sign currently stored in memory will be averaged.

7. Press the Power button to turn off the display.
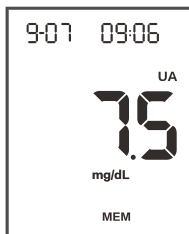
Note: Results from quality control tests will not be included in the averages. When viewing results in memory, these values are marked with a pound sign (⏱) to show that they will not be included in the 7, 14, 30, 60 and 90-day averages.

Note: 7, 14, 30, 60 and 90 days average for ketone and uric acid is not available.

Clearing the Memory

Extreme caution should be used when clearing the memory. This is not a reversible operation. To clear the memory:

1. With the meter off, press and hold the Down Button for 2 seconds. This will turn on the meter and enter the delete mode.

2. Then press and hold both the Up and Down buttons for 2 seconds again to clear the memory.

3. The display will show "MEM" and "---", then the meter will clear its memory and turn itself off after a moment.

MEM
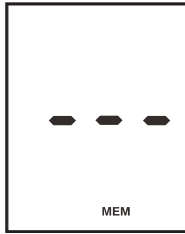
4. If you entered the delete mode but want to exit without deleting the recorded data, press the Power button. This will turn the meter off without deleting any data.

Transferring Records

The meter can transfer stored information to a Windows-based personal computer (PC) using a data transfer cable and software package. To make use of this feature, you need the PLUSMED fasTTest DiagnoPro Data Management Software and a USB data transfer cable from **e-LinkCare.**

1. Install the software to your personal computer (PC) according to the instructions from the PLUSMED fasTTest DiagnoPro Data Management Software Kit.

2. Connect the USB cable to your PC and plug the audio jack of the cable into the meter data port.

3. With the meter off, press and hold the Up button for 2 seconds. This will turn on the meter and enter the "PC" mode.
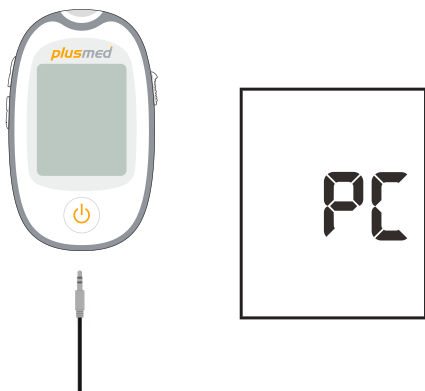
Notes:

● When the meter is in "PC" mode, it does not turn to waiting for sample application mode after strip is inserted into meter.

4. Run the PLUSMED fasTTest DiagnoPro Data Management Software, and refer to the instructions from the software for how to transfer records.

5. During the data transfer, the meter will display "to" and "PC". This indicates the data is being transferred from the meter to the PC.

6. Once the data transfer is complete, the meter will display "End" and "PC".
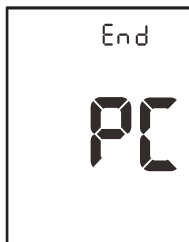
7. After data transfer from meter to PC is completed, the meter will turn itself off. Press the POWER button to turn off the meter.

See the package insert included with your PLUSMED fasTTest DiagnoPro Data Management Software Kit for detailed instructions.

Maintenance

Proper maintenance is recommended for best results.

Replacing the Batteries

Your PLUSMED fasTTest DiagnoPro Multi-Monitoring Meter uses two 3.0 Volt CR 2032 lithium batteries.

When the battery icon ( ) is showing, it means the Meter Battery is running dry. You should replace the Meter Battery as soon as possible. An "E-7" error message will appear if the Meter Battery is too low to perform any more blood glucose tests. The meter will not function until the Meter Battery is replaced.

Instructions:

1. Turn the meter off before removing the battery.

2. Turn the meter over, slide the battery cover in the direction of the arrow to open it.

3. Remove and discard the old battery. Insert two new CR 2032 3.0V coin cell batteries in the battery carrier. Make sure the plus (+) side is facing up.
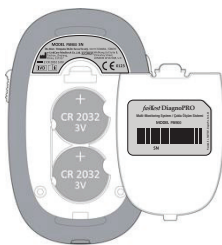
4. Close the battery cover and make sure that it snaps shut.

5. Recheck and reset the clock setting after the battery replacement, if necessary. To set the meter clock, see **Meter Setup Before Testing**.

Caring for Your PLUSMED fasTTest DiagnoPro Multi-Monitoring System

Meter

Your PLUSMED fasTTest DiagnoPro Multi-Monitoring Meter does not require special maintenance or cleaning. A cloth dampened with water and a mild detergent solution can be used to wipe the outside of the meter. Take care to avoid getting liquids, dirt, blood or control solution into the meter through the strip or data ports. It is recommended that you store the meter in the carrying case after each use.

The PLUSMED fasTTest DiagnoPro Multi-Monitoring Meter is a precision electronic instrument. Please handle it with care.

Lancing Device

Use mild soap and warm water to clean with a soft cloth as required. Carefully dry the device thoroughly. Do not immerse the lancing device.

Please refer to the lancing device insert for more details.

Suggested Testing Times and Target Goals

Blood Glucose

Tracking your blood glucose concentration through frequent tests is an important part of proper diabetes care. Your healthcare professional will help you to decide the normal target range for your glucose levels. They will also help you to determine when and how often to test your blood glucose.

Some suggested times are:

- When you wake up (fasting level)

- Before breakfast

- 1 - 2 hours after breakfast

- Before lunch

- 1 - 2 hours after lunch

- Before or after exercise

- Before dinner

- 1 - 2 hours after dinner

- Before bedtime

- After a snack

- At 2 or 3 AM, if taking insulin

You may need to test more often whenever[1]:

- You add or adjust your diabetes medication.

- You think your blood glucose levels may be too low or too high.

- You are ill, or feeling uncomfortable over long periods of time.

Expected blood glucose levels for people without diabetes[2]:

Time	Range, mg/dL	Range, mmol/L
Fasting and Before Meals	70 - 100	3.9 - 5.6
2 Hours after Meals	Less than 140	Less than 7.8

Talk to your healthcare professional to set your own daily target ranges.

Time of Day	Your Target Range
Waking up (Fasting level)	
Before meals	
2 hours after meals	
Bedtime	
2 AM to 3 AM	
Other	

(Note: 1 mmol/L = 18 mg/dl)

Use the logbook to record your blood glucose measurements and related information. Bring the logbook with you when you visit your doctor so that you can determine how well your blood glucose is being controlled. This can help you and your healthcare professional make the best decisions about your glucose control plan.

β-Ketone

Continuous high blood glucose means your body does not have enough insulin to burn glucose, instead it will start burning fat and this produces a chemical called β-Ketone. If left untreated, β-Ketones continues to rise and can result a condition called Diabetic Ketoacidosis, or DKA. This condition may lead to death therefore requires immediate medical attention. It is suggested that if your blood glucose level is above 300 mg/dL or 16.7 mmol/L for two tests in a row, a β-Ketone test needs to be applied immediately.

There are situations when you have positive β-Ketones without blood glucose being too high. Positive β-Ketones are not a problem when blood glucose levels are within range and you are trying to lose weight.

The normal adult blood β-Ketone range for person without diabetes is less than 0.6 mmol/L. Consult with your healthcare professional for the blood β-Ketone range that is appropriate for you. If your blood β-Ketone test result is between 0.6-1.5 mmol/L and glucose is higher than 300 mg/dL, this may indicate development of a medical concern. You need to contact with your healthcare professional for assistance. If your blood β-β-Ketone test result is more than 1.5 mmol/L and glucose is higher than 300 mg/dL, contact with your healthcare professional immediately. This indicates a risk of developing diabetic ketoacidosis (DKA).

Uric Acid

It is important to monitor your Uric Acid level because high levels of uric acid in the blood can cause solid crystals to form within joints. This causes a painful condition called gout. If gout remains untreated, these uric acid crystals can build up in the joints and nearby tissues, forming hard lumpy deposits called tophi. High levels of uric acid may also cause kidney stones or kidney failure.

Most labs that carry out uric acid test will have slightly different definitions of low, Normal and high levels of uric acid in the blood. As such, the information here and all you come across online should be interpreted as a guide only. It will be the decision of your doctor as to whether or not your levels are in the safer regions.

Men	3.4 to 7.0 Milligrams per Deciliter	202 to 416 Micromoles per Liter
Women	2.4 to 6.0 Milligrams per Deciliter	143 to 347 Micromoles per Liter
Children	2.0 to 5.5 Milligrams per Deciliter	119 to 327 Micromoles per Liter

1. Jennifer Mayfield and Stephen Havas, "Self-Control: A Physician's Guide to Blood Glucose Monitoring in the Management of Diabetes – An American Family Physician Monograph"

2. ADA Standards of Medical Care in Diabetes, 2015. Diabetes Care, 2015, Vol.38, Supplement

Comparing Meter and Laboratory Results

Your PLUSMED fasTTest DiagnoPro Multi-Monitoring System and laboratory results both report the glucose, β-Ketone, uric acid concentration in the serum or plasma component of your blood. However, the results may differ somewhat due to normal variation. The Meter results can be affected by factors and conditions that do not affect laboratory results in the same way. See PLUSMED fasTTest DiagnoPro GLU GOD/GLU GDH /KET/UA Test Strips' package insert for typical accuracy and precision data, and for important information on limitations.

To ensure a reasonable comparison, follow these guidelines.

Before you go to the lab:

- Bring your meter, test strips and control solution with you to the lab.
- Make sure your meter is clean.
- Perform a quality control test to make sure the meter is working properly.
- Comparisons will be more accurate if you do not eat for at least four hours (preferably eight hours) before testing.

At the lab:

- Wash your hands before obtaining a blood sample.
- Obtain blood samples for a laboratory test and for your meter within 10 minutes of each other. This will ensure an accurate comparison of results.
- Never use your meter with blood that has been placed in test tubes containing fluoride or other anticoagulants. This will cause falsely low results.

Troubleshooting Guide

The meter has built-in messages to alert you of problems. When error messages appear, note the error number, turn off the meter and then follow these instructions.

| Display	Causes	Solution
Meter fails to turn on	Battery may be damaged or not be charged	Replace battery.
	The operation environment is too cold	If meter has been exposed to or stored in cold conditions, wait 30 minutes to allow the meter to reach room temperature then repeat the test.
E-0	Internal calibration check error	If the problem persists, please contact your local distributor.
E-1	Power On self-check error	Remove the battery for 30 seconds and then put it back and turn meter on again. If the problem persists, please contact your local distributor.
E-2	Test strip is contaminated or used, or being exposed to moisture.	Repeat the test with a new test strip.
E-3	Sample was applied to the test strip too soon	Repeat the test and apply sample after blood drop/test strip symbol appears.
E-4	Strip is removed during testing	Repeat the test slowly and steady.
E-5	Insufficient sample	Repeat the test and apply enough sample to fill the test strip check window.
	Sample application error due to late sample re-dosing	Repeat the test and apply enough sample to fill the test strip check window within 3 seconds.
E-6	Sample application improperly or HCT value out of range	Check the blood HCT value and Repeat the test.

⊡	Battery is running out. Only allow maximum 5 tests	Replace the battery as soon as possible.
E-7	Battery is discharged and the meter does not allow more tests until replacement with a new battery	Replace the battery and reset, then repeat the test.
E-8	The operation Temperature is anomalous changed	Please double check the operation condition is steady, then repeat the test.
HIt	Temperature has exceeded the operating temperature of the system	Move to a cooler environment and repeat the test.
LOt	Temperature is below the operating temperature of the system	Move to a warmer environment and repeat the test.
E-9	Hardware damaged	Please contact your local distributor for meter replacement
E10	Code chip failure or damaged	Replace the code chip and perform the test again.
E11	Code chip not matched	Replace the calibration chip and perform the test again
E12	Communications failure; This Error may also appear when a test strip is inserted and start flashing "---" while connect to a cable OR when the meter is ready for blood dropping / counting down for a test while connect to a cable	There is an error in transferring data to the PC. See the package insert included in the PLUSMED fasTTest DiagnoPro Data Management Software for troubleshooting.

Specifications

Feature	Specification
Parameter	Blood Glucose, Blood β-Ketone, and Blood Uric Acid
Measurement Range	Blood Glucose: 0.6 - 33.3 mmol/L (10 - 600 mg/dL) Blood β-Ketone: 0.0 - 8.0 mmol/L Uric Acid: 3.0 - 20.0 mg/dL (179 - 1190 μmol/L)
Hematocrit Range	Blood Glucose and β-Ketone: 15% - 70 % Uric Acid: 25% - 60%
Result Calibration	Plasma-equivalent
Sample	When testing β-Ketone, Uric Acid or Blood glucose with Glucose Dehydrogenase FAD-Dependent, use fresh capillary whole blood, arterial or and venous Blood samples; When testing Blood glucose with Glucose Oxidase: use fresh capillary whole blood
Minimum Sample Size	Blood Glucose: 0.7 μL Blood β-Ketone: 0.9 μL Blood Uric Acid: 1.0 μL
Test Time	Blood Glucose: 5 seconds Blood β-Ketone: 5 seconds Blood Uric Acid: 15 seconds
Units of Measure	Blood Glucose: The meter is preset to either millimole per liter (mmol/L) or milligrams per deciliter (mg/dL) depending on the standard of your country.
	Blood β-Ketone: The meter is preset to millimole per liter (mmol/L)

	Blood Uric Acid: The meter is preset to either micromoles per liter (μmol/L) or milligrams per deciliter (mg/dL) depending on the standard of your country.
Memory	Blood Glucose: 500 tests (GOD + GDH) Blood β-Ketone: 100 tests Blood Uric Acid: 100 tests
Automatic Shutoff	2 minutes
Meter Size	86 mm × 52 mm × 18 mm
On/Off Source	Two CR 2032 3.0V coin cell batteries
Battery Life	Around 1000 tests
Display Size	32 mm × 40 mm
Weight	53 g (with battery installed)
Operating Temperature	Glucose and Ketone: 5 - 45 ºC (41 - 113ºF) Uric Acid: 10 - 40 ºC (50 - 104ºF)
Operating Relative Humidity	10 - 90% (non-condensing)
Operating Altitude	0 - 10000 feet (0 - 3048 meters)
Data Port	19200 baud, 8 data bits, 1 stop bit, no parity

Index of Symbols

	Consult instructions for use
IVD	For *in vitro* diagnostic use only
	Store between -20 – 50 ºC (-4 – 122 ºF)
	Contains sufficient for \<n\> tests
	Use by
LOT	Lot Number
	Manufacturer
EC REP	Authorized Representative
STERILE R	Sterilized using irradiation
REF	Catalog #
MODEL	Model Number
SN	Serial Number
	Do not reuse
	6 months expiry date from the date of first open vial

	Do not dispose along with household waste
	Fragile, handle with care
	This Side Up
	Keep away from sunlight and heat
	Keep Dry

-20°C – 50°C

IVD

CE 0123
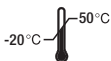
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