

# ACCUGENCE®

## Multi-monitoring System

MODEL PM930

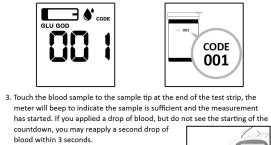
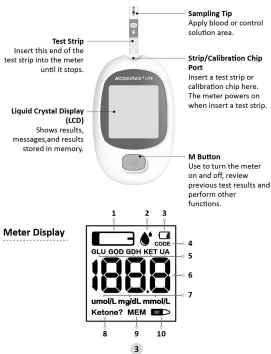
# LITE

### Quick Guide

Read this quick guide carefully before you start testing.



#### Glance of Meter and Test Strip



3. Touch the blood sample to the sample tip at the end of the test strip, until the meter beeps 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 blood within 5 seconds.

**DO NOT:**

- Apply the sample to the front or back of the test strip.
- Squeeze the blood drop onto the test strip.
- Press the finger against the test strip.

4. The meter will count down from 4 (for Uric Acid Test Strips will count down from 14) to 1 and then display the measurement results. The results will be saved in the meter's memory automatically.

**Note:** Dispose of blood samples and materials carefully. Follow proper precautions and obey all regulations when disposing of blood samples and materials.

#### 9 Troubleshooting Guide

Display	Causes	Solution
<b>E-1</b>	Battery may be damaged or not be charged	Replace battery.
<b>E-2</b>	Internal calibration 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.
<b>E-3</b>	Test strip is contaminated or, or being exposed to moisture	Repeat the test and apply sample after blood dries completely.
<b>E-4</b>	Strip is removed during testing	Repeat the test with a new test strip.
<b>E-5</b>	Insufficient sample	Repeat the test and apply enough sample to fill the test strip check window.
<b>E-6</b>	Sample application error due to late sample re-loading	Repeat the test and apply enough sample to fill the test strip check window within 3 seconds.

Thank you for choosing ACCUGENCE® LITE Multi-Monitoring System (Model: PM 930).

ACCUGENCE® Blood Glucose Test Strips, ACCUGENCE® Blood  $\beta$ -Ketone Test Strips and ACCUGENCE® Blood Uric Acid Test Strips with ACCUGENCE® LITE Multi-Monitoring System are limited to healthcare professional use only. ACCUGENCE® LITE Multi-Monitoring Meter with ACCUGENCE® Blood  $\beta$ -Ketone Test Strips are intended for use for the quantitative measurement of  $\beta$ -hydroxybutyrate ( $\beta$ -ketone) in fresh capillary whole blood or venous whole blood. It should **NOT** be used to diagnose DKA, and it is limited for professional use only.

ACCUGENCE® LITE Multi-Monitoring Meter with ACCUGENCE® Blood Uric Acid Test Strips are intended for use for the quantitative measurement of uric acid in fresh capillary whole blood or venous whole blood.

**Note:** There are two types of ACCUGENCE® Blood Glucose test strips available, ACCUGENCE® Blood glucose test strips using glucose oxidase (GOD) or ACCUGENCE® Blood glucose test strips using glucose dehydrogenase (GDH-dependent). When ACCUGENCE® Blood Glucose Test Strips (Glucose Oxidase) are used, only fresh capillary whole blood is allowable to be used for testing. When ACCUGENCE® Blood Glucose Test Strips (Glucose Dehydrogenase GDH-dependent) are used, fresh capillary whole blood or venous whole blood is allowable to be used for testing.

To ensure accurate results from the system, please follow these guidelines carefully:

- Read instructions before use.
- The device should not be used for patients who are dehydrated, in shock, critically ill or in a hyperosmolar state.
- Use the associated calibration chip that accompanies each type of test strip when tests are applied. Use with single-use, auto-dialing lancing device.
- Keep out of reach of children.

Number	Symbol	Indicator	Means
1		Strip icon	Indicate when to apply the sample.
2		Blood Drop icon	Blinking before applying the sample.
3		Low Power icon	Warns you when you should replace the battery.
4	<b>CODE</b>	Code icon	Indicates the test strip calibration code number.
5	<b>GLU GOD/ GLU GDH/ KET/ or UIC</b>	Strip type or Test Parameter icon	Indicates different strip type or test parameter. GLU GOD/ GLU GDH means the meter is currently performing the blood glucose test with strip of which the code number is 001 means blood $\beta$ -ketone test, UIC stands for blood uric acid test.
6	<b>1888</b>	Test Result Area	Indicates the test result and calibration code number.
7	<b>umol/L, mg/dL, mmol/L</b>	Measurement Unit	Measurement units differ for different test parameters, mg/dL, and mmol/L are for blood glucose, mmol/L are for $\beta$ -ketone, mg/dL, and a mmol/L are for uric acid. <b>Note:</b> When blood glucose testing is performed, only one unit of measure will be displayed on the meter and it cannot be adjusted.
8	<b>Ketone?</b>	Blood Ketone Result Symbol	Appears when the blood glucose concentration is above 16.7 mmol/L (300 mg/dL). This simply suggests that a $\beta$ -ketone test is recommended. <b>Note:</b> This symbol does not mean that the system has detected $\beta$ -ketones. It recommends that a $\beta$ -ketone test should be taken.
9	<b>MEM</b>	Memory	Shows a test result stored in memory.
10		QC icon	Indicates a test result when running quality control.

#### 6 Control Test

The quality control test confirms that the test strip 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 results are not working properly.
- When you suspect the test results are inaccurate.
- When you suspect the meter is damaged.
- After cleaning the meter.
- At least once a week.

Please contact your local distributor for information on ordering the ACCUGENCE® Control Solution Kit. The kit contains Control Solution 1, Control Solution 2 and Control Solution 3 for blood glucose and  $\beta$ -ketone, and Control Solution 1 and Control Solution 2 for uric acid.

"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  $\beta$ -ketone test is recommended.



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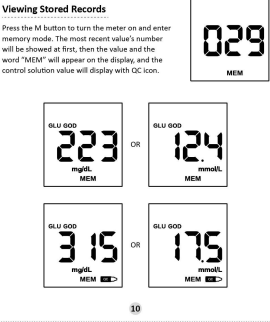
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#### Meter Use and Precautions:

1. Wait for the Blood Drop / Strip Symbol to appear before applying the sample.
2. The meter is pre-set to display depending on which unit of measure is standard in your country. Blood glucose concentration is either millimole per liter (mmol/L) or milligrams per deciliter (mg/dL), uric acid concentration is either milligrams per deciliter (mg/dL) or micromole per liter ( $\mu$ mol/L). This unit of measure cannot be adjusted.
3. The meter will shut off automatically 2 minutes after inactivity.
4. Do not get water or other liquids inside the meter.
5. Keep the strip port area clean.
6. Keep the meter dry and avoid exposing it to extreme temperatures or humidity. Do not leave it in your car.
7. Do not put the meter or get it wet. If you do get the meter or get it wet, check the meter by running a quality control test.
8. Do not take the meter apart. Taking the meter apart will void the warranty.
9. 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.

#### 7 Recall the Meter Memory

The meter automatically stores up to 150 test records. The oldest record will be erased to make room for a new one if memory reaches its limit.

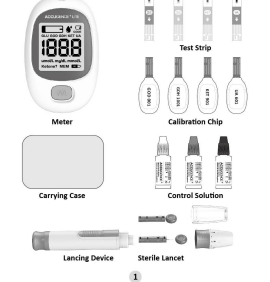


#### 10 Specifications

Feature	Specification
Parameter	Blood Glucose, Blood $\beta$ -Ketone, and Blood Uric Acid
Measurement Range (Hemoglobin) Range	Refer to the test strip package insert.
Sample Type	Blood Glucose: 5 seconds Blood $\beta$ -Ketone: 5 seconds Blood Uric Acid: 15 seconds
Minimum Sample Size	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 $\beta$ -Ketone: The meter is preset to millimole per liter (mmol/L). Blood Uric Acid: The meter is preset to either micromole per liter ( $\mu$ mol/L) or milligrams per deciliter (mg/dL) depending on the standard of your country.
Units of Measure	150 test records
Memory	2 minutes
Automatic Shutoff	79 mm $\times$ 50 mm $\times$ 14.5 mm
Size	One CR 2032 3.0V coin cell batteries
On/Off Switch	Around 1000 tests
Battery Life	30 mm $\times$ 32 mm
Display Size	36 g (with battery installed)
Weight	Blood Glucose and $\beta$ -Ketone: 5 $\times$ 45 $\times$ 41 (11 $\times$ 11 $\times$ 9) Blood Uric Acid: 38 $\times$ 48 $\times$ 50 (10 $\times$ 12 $\times$ 12)
Operating Temperature	10 - 90% (non-condensing)
Operating Relative Humidity	0 - 1000% feet (0 - 3048 meters)

#### 2 Getting Started

Before testing, read the instructions carefully and learn about all the components of the ACCUGENCE® LITE 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.

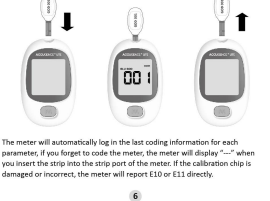


#### 3 Installing Battery

The battery may be pre-installed in the meter. One CR2032 3.0V coin cell battery is required. You may pull out the plastic insulation strip before use the meter.

#### 4 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 calibration 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 calibration chip in the strip box. With the meter turned off, insert the calibration chip into the strip port of the meter. It should easily snap into place. Once you code the meter, you can take out the calibration chip and start testing.



If you are using the meter for the very first time, the meter display will show three dashed lines (---) and the word "MEM". This shows that no data has been stored in memory.

#### Clearing the Memory

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

1. Press the M button to turn the meter on and enter the memory mode. Press the M button again to review the results until the words "End" and "MEM" will appear on the display.
2. Then press and hold the M button for 3 seconds, the words "0E" and "MEM" will appear on the display. If no operation is done in 2 minutes, the meter will turn off without clearing the memory.
3. Press and hold the M button again until the words "0E" and "MEM" appear on the display, then press "---" and "MEM", indicating the memory is cleared. The meter will turn itself off after a while.
4. If you entered the delete mode but want to exit without deleting the records, tap the M button, the meter will enter the memory mode without deleting any data.

#### 11 Index of Symbols

Symbol	Consult Instructions for use
	For in vitro diagnostic use only
	Store between -20 $\times$ 50 $\times$ C (-4 $\times$ 122 $\times$ F)
	Contains sufficient for <no tests>
	Use by
	Lot Number
	Manufacturer
	Sterilized using irradiation
	Ref Catalog
	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
	Keep away from sunlight and heat
	Keep dry

#### Components Descriptions

1. ACCUGENCE® LITE Multi-Monitoring Meter: Reads the test strips for blood glucose,  $\beta$ -ketone, uric acid and displays each concentration.
2. Test Strips: Strips with a chemical reagent system used with the meter to measure glucose,  $\beta$ -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: Single-use, sterile lancet is used with the lancing device to obtain blood samples. Discard it after a single use.
6. Control Solution: Verifies the proper operation of the ACCUGENCE® LITE Multi-Monitoring System by checking the test strips and meter against a pre-calibrated control solution, which are available in the ACCUGENCE® LITE Multi-Monitoring System Control Solution package which is sold separately. **Note:** For Blood Glucose and  $\beta$ -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. Caring Card: Provides portability for testing.
8. Quick Guide: Provides detailed instructions on using the ACCUGENCE® LITE Multi-Monitoring System.

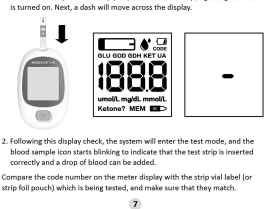
#### 5 Blood Glucose/ $\beta$ -Ketone/Uric Acid Tests

**Step 1 - Getting a Drop of Blood**

The ACCUGENCE® LITE Multi-Monitoring System requires a very small drop of blood which may be obtained from the fingertip or ear. Please read the lancing device insert for the instructions.

#### Step 2 - Testing Blood Glucose/ $\beta$ -ketone/Uric Acid

Insertion of a new test strip at any time will cause the meter to automatically enter the test mode. Since the testing steps are the same, here make an example of blood glucose testing by ACCUGENCE® Blood Glucose Test Strips (Glucose Oxidase) below:



#### 8 Maintenance

Proper maintenance is recommended for best results.

1. **Meter**  
The ACCUGENCE® LITE 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 ACCUGENCE® LITE Multi-Monitoring Meter is a precision electronic instrument. Please handle it with care.
2. **Lancing Device**  
Use mild soap and warm water to clean with a soft cloth as required. Carefully dry the device thoroughly. Do not disassemble the lancing device. Please refer to the Lancing Device insert for more details.

#### 12 Warranty Card

Please complete the warranty card that came with this product and mail it to your dealer to register your purchase and validate your warranty. If you make a claim for any reason other than obvious abuse within the first (5) years from purchase, we will replace it with a new meter free of charge. For records, you will receive the purchase date of your product here.

Date of purchase: \_\_\_\_\_  
Model Number: \_\_\_\_\_  
Meter Serial Number: \_\_\_\_\_  
The problem description: \_\_\_\_\_

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

#### Local Dealer Information:

You expect: \_\_\_\_\_  
Replace a new meter \_\_\_\_\_  
Return after warranty \_\_\_\_\_

Signature: \_\_\_\_\_  
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