

ACEZIN SUPERGold

Blood Glucose and Ketone Monitoring System

FCC Caution



This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If his equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

CAUTION:

To assure continued FCC compliance:

1. Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.
2. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

ACEZIN SUPERGold

Blood Glucose and Ketone Monitoring System

Model: AM100 PK-B /
AM100 PK

User Guide

Before You Begin

PLEASE READ THIS BEFORE USING.

The following basic safety precautions should always be taken.

1. Close supervision is necessary when the device is used on or near children, handicapped persons or invalids.
2. Use the device only for the intended use described in this user guide.
3. Do not use test strips and control solutions which are not supplied by the manufacturer.
4. Do not use the device if it is not working properly, or if it has suffered any damage.
5. Before using any product to test your blood glucose, read all instructions thoroughly and practice the test. Do all quality control checks as directed and consult with a diabetes healthcare professional.
6. Do not use this meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electrical or electronical equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.
7. KEEP THESE USER GUIDE WITH YOU.

Intended Use

The system is intended for home testing to monitor the blood glucose (β -D-glucose) levels and blood ketone (β -hydroxybutyrate) levels in fresh capillary whole blood from fingertip and venous whole blood. The system is for In-vitro use only, and it is indicated to be used by diabetics at home or in a clinical setting by professional healthcare personnel to measure the glucose concentration for aiding diabetes management. It should not be used for the diagnosis of diabetes or for the testing of newborns. [IVD]

IVD	For In vitro diagnostic use		Temperature limitation / Store at
	Please consult instructions for use		Use by /Expiry date
	Do not reuse		Manufacturer
LOT	Lot number		Caution, consult accompanying document
	Keep dry		Keep away from sunlight
	Humidity limitation	EC REP	EU representative.
CE 0123	This product fulfils the requirements of Directive 98/79/EC in vitro diagnostic medical device.		

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P/N: M709-000000-135 VER: 001

Principle of Measurement

We design ACEZIN *SUPERGold* Blood Glucose and Ketone Monitoring System by using the latest biosensor technology. In blood glucose measuring, it measures the glucose levels of the blood specimen by using a disposable dry reagent strip which can produce an electrical current. And the current will transfer to the meter for measurement. The amount of the current is proportional to the amount of glucose present in the blood sample. Test results are "plasma equivalent". In blood ketone measuring, it measures the ketone levels of the blood specimen with a disposable dry reagent strip. When the chemicals on the strips react with blood can produce an electrical current. And the current will be transferred to the meter for measurement. The amount of the current is proportional to the amount of ketone present in the blood sample. Test results are "plasma equivalent".

1. Apply only capillary whole blood sample to test your blood glucose. Applying other substances or plasma, serum will cause wrong results.
2. Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
3. Test results below 60 mg/dL (3.3 mmol/L)*1 indicates low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3 mmol/L)*2 indicates high blood glucose (hyperglycemia). If your results are below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), repeat the test, and if the results are still below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), consult your healthcare professional immediately. Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
4. Abnormal red blood cell counts (hematocrit level above 70%) may cause false results. Please consult your healthcare professional if you do not know your hematocrit level.

SIDE A : 1. Getting To Know Your System

2. Prepare For Blood Sampling

SIDE B : 3. Performing Blood Glucose Test

4. Memory Recall

5. Control Solution Testing

6. Caring For Your Meter And Test Strip

7. System Specifications

8. Performing Blood Ketone Test

9. Display Messages And Problem-Solving Guide

10. Transmission

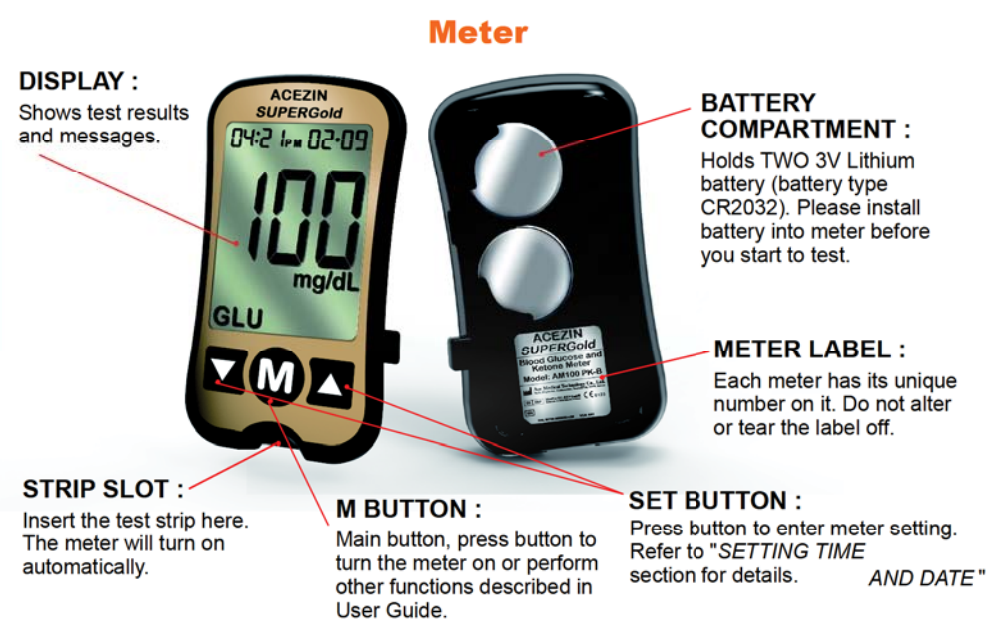
⚠ Caution

1. To make sure that you operate AM100 PK Blood Glucose and Ketone Monitoring System safely and accurately, please follow the user's manual.
2. Please keep AM100 PK Blood Glucose and Ketone Monitoring System away from any liquid or sprays, keep them dry.
3. Do not use AM100 PK Blood Glucose and Ketone Monitoring System on purposes outside "Intended Use".
4. Only use accessories supplied or recommended by the manufacturer.
5. Avoid severe impact on the meter. It may cause malfunction.
6. Do not take AM100 PK Blood Glucose and Ketone Meter apart, or modify anything. Such action may void your warranty.
7. Do not place anything on top of AM100 PK Blood Glucose and Ketone Meter.
8. Keep the whole AM100 PK Blood Glucose and Ketone Monitoring System away from children. They may choke on battery, or tiny component parts by accident.
9. Keep AM100 PK Blood Glucose and Ketone Meter free from dust, hair, etc. Store the meter in its container after use.
10. If you feel you are suffering from severe dehydration, stop using and consult healthcare professionals right away.
11. If your symptoms are not consistent with blood glucose test results and you have followed all instructions this manual, seek your healthcare professional for help.
12. Dispose of medical waste per local regulations.
13. Warning for potential biohazard: Healthcare professionals using this system on multiple patients should be aware that all products or objects that come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral disease. So the healthcare professionals should wear disposable gloves and have an inoculation regularly to prevent infections.

1. Getting To Know Your System

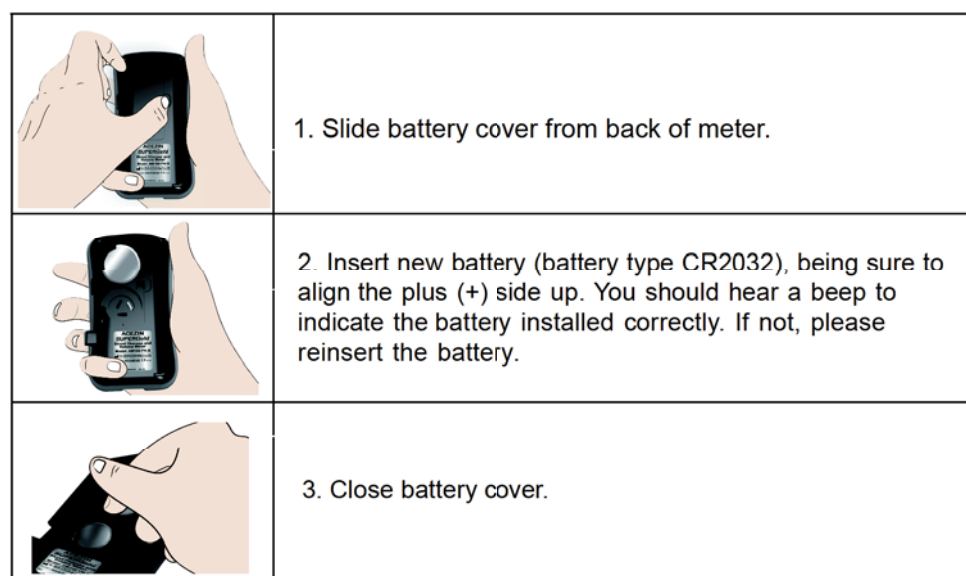
The ACEZIN *SUPERGold* meter is available as a meter only or as a meter kit. Please review the contents of your purchase to confirm that all the components are included listed on the side of your meter box.

Use ACEZIN *SUPERGold* Blood Glucose and Ketone Meter only with ACEZIN *SUPERGold* Blood Glucose Test Strips and ACEZIN *SUPERGold* Blood Ketone Test Strips and ACEZIN Control Solution.



1. 1&2. Hour & Minute/Year
3. Month & Date
4. Memory: Appear while LCD displays past results
5. DAY AVG: Appear while LCD displays average of past 7 / 14 / 30 / 60 / 90 days result.
6. Wireless transmission
7. Apply Blood Symbol: Your meter is ready to measure.
8. Decimal Point: Appears when LCD displays blood glucose result in mmol/l unit or ketone result.
9. mg/dl: This device can display results in unit mg/dl.
10. mmol/l: This device can display results in mmol/l unit.
11. Low Battery Symbol: Appears when battery is low
12. Temperature Symbol: Appears when ambient temperature exceeds operating temperature.
13. Control Solution Test Symbol: Appears while performing Control Solution Mode.
14. Pre-meal or Post-meal Symbol: Indicates whether the test result is taken before or after meal.
15. GLU symbol: Appears When meter under glucose mode.
16. KET symbol: Appears When meter under ketone mode.

How to replace the battery



⚠ NOTE:

1. Replacing the battery does not affect the test result stored in memory. However the time and date may need to re-set.
2. As with all small objects, the battery should be kept away from small children as a safety precaution. If the battery is swallowed, seek medical assistance immediately.
3. Batteries might leak chemicals if not used for a long time. Remove the batteries if you are not going to use the device for extended (i.e., 3 months or more).
4. Please discard the product or the batteries properly according to the regulations of your country.

SETTING TIME AND DATE

Please install battery first and set correct time and date before you begin to test.

	STEP 1. Enter Setting Mode Start with the meter off. Press ▲ & ▼ BUTTON. The meter will turn on and enter the setting mode.
	STEP 2. Set the Year The year appears with the number flashing. Press ▲ & ▼ BUTTON to obtain the desired year. Press M BUTTON to confirm and move to next month setting.
	STEP 3. Set the Month The month appears with the number flashing. Press ▲ & ▼ BUTTON to obtain the desired month. Press M BUTTON to confirm and move to next date setting.
	STEP 4. Set the Date The date appears with the number flashing. Press ▲ & ▼ BUTTON to obtain the desired date. Press M BUTTON to confirm and move to next hour setting.
	STEP 5. Set the Hour The hour appears with the number flashing. Press ▲ & ▼ BUTTON to obtain the desired hour. Press M BUTTON to confirm and move to next minute setting.
	STEP 6. Set the Minute The minute appears with the number flashing. Press ▲ & ▼ BUTTON to obtain the desired minute. Press M BUTTON to confirm and move to next unit setting.
	STEP 7. Set the Unit of Measurement The existing unit will appear and flash. If you do not want to change the unit, press M BUTTON to skip this step. If you want to change the unit, press and hold the ▲ & ▼ BUTTON ; press M BUTTON to confirm and the meter will enter to next delete all memory setting.
	STEP 8. Delete Memory When the dEL symbol and the flashing memory symbol appear on the display, you can choose to clear the memory. If you do not want to clear the memory, press the M BUTTON again to skip this step. If you want to clear ALL memory, press and hold ▲ & ▼ BUTTON for 3 seconds. The "—" image will appear on the LCD screen to indicate that all memory has been deleted.
	STEP 9. Complete Setting After deleting memory, the meter will display "OFF" before shut down. The meter setting is now completed.

⚠ IMPORTANT :

1. The time, date and unit of measurement can ONLY be changed in the setting mode. Therefore, when you perform a blood glucose testing, it is not possible to change those parameters.
2. Your meter displays 7, 14, 30, 60, 90 days averages which you can access from the meter memory. These averages are calculated from the date of your latest result to 7, 14, 30, 60, 90 days before.
3. Your meter displays test results in milligram per deciliter (mg/dL) or millimoles of glucose per liter (mmol/L). Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment. Please always consult with your healthcare professionals before you reset the unit of measure.
4. While the meter is in the setting mode, if no button is pressed for 30 seconds, the meter will turn off automatically.

2. Prepare For Blood Sampling

Adjustable Lancing Device

Your lancing device and lancets are used for obtaining capillary blood samples from the puncture site.

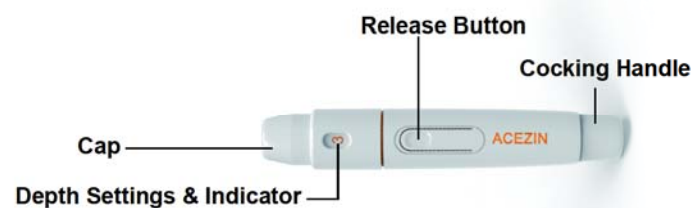
Lancet

Protective cap

⚠ Important Lancing Device and Lancets Information

1. Ⓢ Lancet is for single use only.
2. Keep lancing device and lancets clean.
3. Use caution when removing the used lancet from the device and when disposing the used lancet.

IMPORTANT : The meter and lancing device are for single patient use. Do NOT share them with anyone including other family members ! Do NOT use on multiple patients !



Setting your Lancing Device

1. Screw off the cap of lancing device. Insert a lancet into the lancet holder and push down until it is fully seated.
2. Twist off the protective cap until it separates from the lancet.
3. Replace the lancing device cap and set the puncture depth to the desired number. To select the best depth:

For delicate skin
For normal skin
For thick or callused skin
4. Pull back the Sliding Barrel until it makes a click, and then release. If it does not click, the device may have been cocked when the lancet was inserted.