

# FCC Caution

## ACEZIN HI Gold Blood Glucose Monitoring System



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 HIGold Blood Glucose Monitoring System

Model: AM100 PD-B / AM100 PD

## User Guide

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
CE 0123	This product fulfils the requirements of Directive 98/79/EC in vitro diagnostic medical device.	

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**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**

SIDE A

## 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 electronic 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 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.

### Principle of Measurement

We design ACEZIN HIGold Blood Glucose 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".

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.

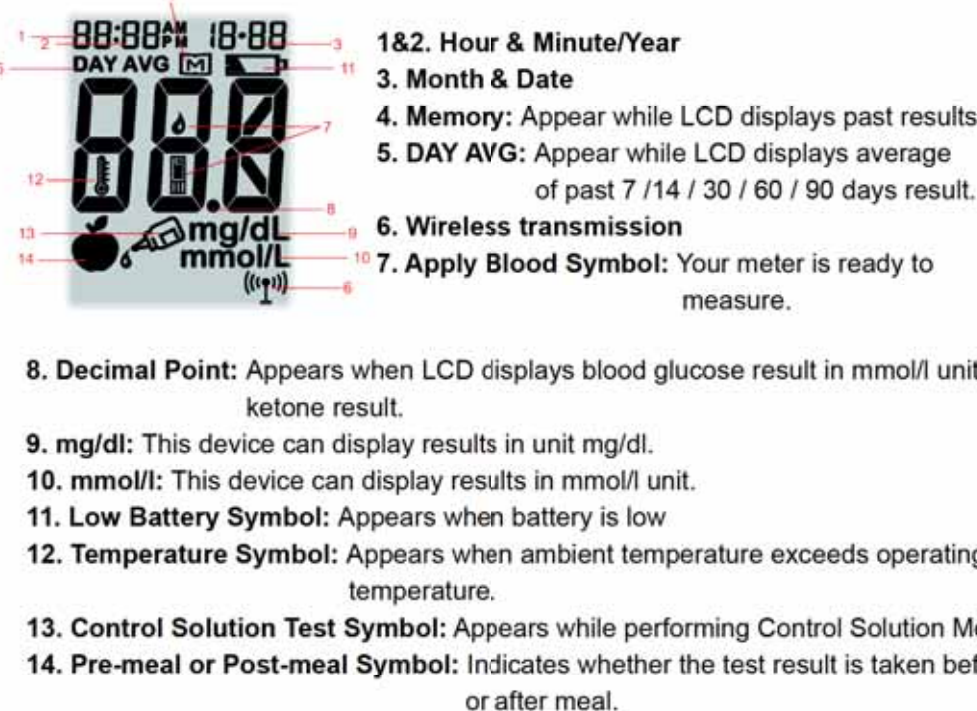
### Caution

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.
14. This monitor is not intended for use in the MRI environment.
15. For indoor use. Operating Altitude below to 3000 m.
16. Use environment pollution degree 2.

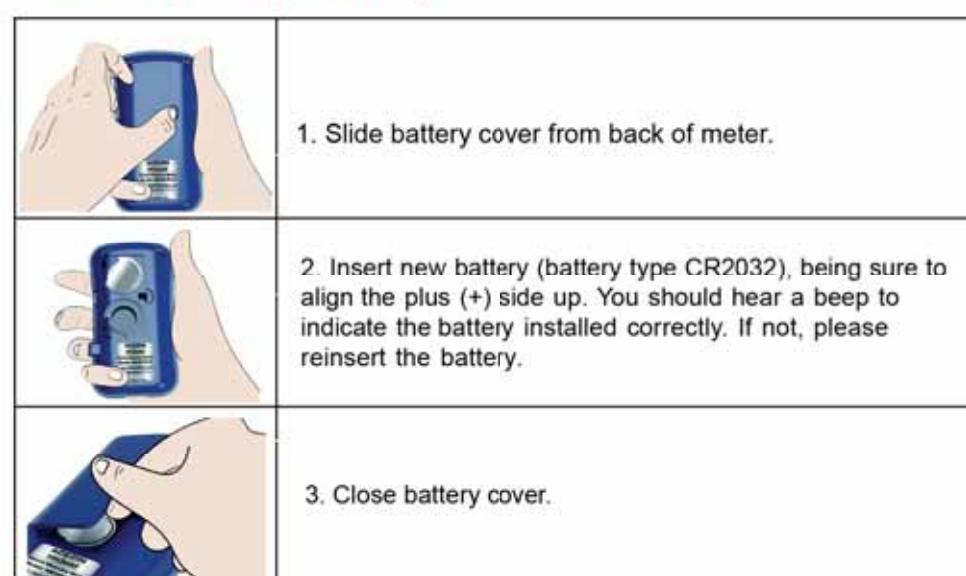
## 1. Getting To Know Your System

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.



### 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.

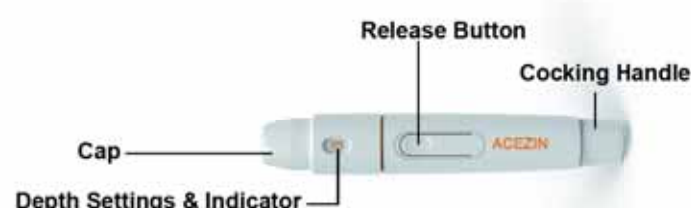
	<b>STEP 1. Enter Setting Mode</b> Start with the meter off. Press ▲ & ▼ BUTTON. The meter will turn on and enter the setting mode.
	<b>STEP 2. Set the Year</b> The year appears with the number flashing. Press ▲ & ▼ BUTTON to obtain the desired year. Press M BUTTON to confirm and move to next month setting.
	<b>STEP 3. Set the Month</b> 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.
	<b>STEP 4. Set the Date</b> 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.
	<b>STEP 5. Set the Hour</b> 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.
	<b>STEP 6. Set the Minute</b> 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.
	<b>STEP 7. Set the Unit of Measurement</b> 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.
	<b>STEP 8. Delete Memory</b> 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.
	<b>STEP 9. Complete Setting</b> 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.



### 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.



## 3. Performing Blood Glucose Test

**1. Wash Your Hands and the Puncture Site :** hands in warm, soapy water. Rinse and dry completely. Warm your fingers to increase blood flow.



**2. Insert Test Strip :** Remove a new test strip from vial. Be sure to tightly replace vial cap after removing test strips. Insert test strip immediately into strip slot as illustrated. The meter turns on automatically. When the blood symbol blinking, you are ready to perform a test.



**3. Select and Lance a Puncture Site**  
Hold the prepared lancing device firmly against the side of your fingertip. Press release button.



**4. Obtain a Blood Sample :** Gently massage your finger or puncture site to obtain the required blood volume. To perform the test, you need only 0.85 µL of blood sample. Do not smear the blood sample. To obtain best accurate result, wipe off the first drop of blood and gently squeeze another drop of blood.



The blood needs to be in the form of droplets!



**5. Apply Blood Sample :** Apply the blood sample to the opening of absorbent channel of test strip until the confirmation window is fully covered with blood. Then the meter begins to count down and displays the test result in 5 seconds.



**6. Read Your Result :** Meter beeps when blood is detected, and user can then move your finger away. Glucose test result displays in 5 seconds. The result is shown on the display.



**7. Pre/Post Meal :** With Meal Comment Function on, test result appears with flashing symbol, depending on the setting.



**8. Remove Strip to Turn Meter Off :** Your blood glucose result is automatically stored in the meter memory. Turn the meter off by removing the test strip. Discard the used strip and lancet safely in a puncture resistant container. User can either take out the used strip by pushing and slide the Strip Eject button or remove the test strip directly to shut the meter off.



**8. Remove the Lancing Device Cap when finished:** Put the Protective Cap back onto the exposed needle of the lancet.



**9. Direct the lancing device away from you and slide the Lancet Ejector in a forward motion, disposing the lancet in an approved container.**

## 5. Control Solution Testing

If your ACEZIN control solution did not come with an ACEZIN Control Solution Instruction, the following information shall take the place of the instruction.

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

### Why perform a control solution test?

- To ensure that your meter and test strip are working properly together.
- To allow you to practice testing without using your own blood.

### When should the control solution test be performed?

- When you first get your ACEZIN HIGold meter. Before using this system to test your blood, you can practice the procedure by using control solution. When you can do three tests in a row that are within the expected range, you are ready to test your blood.
- Once a week (to make sure that you continue to get accurate results)
- When you begin using a new vial of test strips.
- Whenever you suspect that the meter or test strips are not working properly.
- When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate.
- When test strips are exposed to extreme environmental conditions.
- If you drop the meter.

### Important Control Solution Information

- Check the expiration date on the control solution bottle. Do not use if expired.
- Control solution, meter, and test strips should come to room temperature (68-77 °F/20-25°C) before testing.
- Shake the bottle before use, discard the first drop of control solution after squeezing, wipe off the dispenser tip to avoid contaminations. These steps ensure you will get a good sample and an accurate result.
- Record the discard date on the bottle when you open a new bottle of control solution.

**NOTE :** 1. There are two levels of control solution (medium and high) available to purchase. Please contact with your local distributor when required.  
2. The control solution range printed on the test strip vial is for ACEZIN Control Solution only. It is used to test meter and strip performance. It is not recommended range for your blood glucose level.

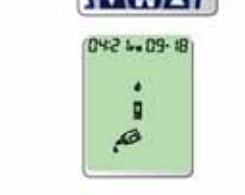
### Composition:

1. D-Glucose	5. Disodium EDTA
2. Polyvinyl acetate (aqueous emulsion)	6. Food Pigment Red No.6
3. Fumed silica	7. Antifoaming agent
4. Sodium Benzoate	(Polyethylene Glycol 4000)

### How to Perform a Control Test



**1. Insert Test Strip :** Insert a new test strip into the strip slot, the meter will activate.



**2. Mark as a Control Solution Test :** After the blood symbol (b) appears, press M BUTTON and "c" appears on the display indicating you are in the Control Solution Mode. The meter will not store your test result in the memory when you preset the test as a control solution test. If you decide not to perform a control solution test, press M BUTTON again and the "c" will disappear.



**3. Squeeze a drop of Control Solution :** Shake control solution bottle well. Remove the cap. Squeeze bottle, discard the first drop and wipe off the dispenser tip with a clean tissue paper or cotton swab. Squeeze a drop on a clean non-absorbent surface.



**4. Apply Control Solution :** Apply the drop to the opening of the strip absorbent channel until the meter beeps. The meter begins to count down.



**5. Check if the test result is in range:** After the meter counts down from 5 to 1, the test result shows up. Compare the test result with the range printed on the test strip vial. The result should fall within the printed range.

**NOTE :** 1. DO NOT APPLY THE CONTROL SOLUTION DIRECTLY TO THE TEST STRIP! Overdosed solution may give inaccurate result.  
2. Repeat test if test result falls outside the control range stated on the test strip label. If subsequent test remains to produce unacceptable result, the meter or test strip may be faulty. DO NOT use the system. Contact us or your local distributor for help.

## 4. Memory Recall

The ACEZIN HIGold Meter automatically stores 1000 glucose test results, letting you review them in order from the most recent to the oldest. The meter also calculates and displays 7, 14, 30, 60 and 90-day averages. You can review the individual or average test result by entering the memory mode.

### Recall the Memory



#### STEP 1. Enter the Memory Mode

PRESS M BUTTON to turn on the meter, and press M bottom again to enter memory mode.



#### STEP 2. Recalling Average Test Results

When entering the memory mode, the 7-day average will appear. If you continue to press the M BUTTON, the 14-day, 30-day, 60-day and 90-day averages will display in order.



#### STEP 3. Recalling Individual Test Results

After 90-day average, the most recent test result with date and time will be shown. Press M BUTTON once and the next most recent test result will appear. Each time you press and release the M BUTTON, the meter will recall up to your last 1000 test results in order. When the memory is full, the oldest result is dropped as the newest is added.



#### STEP 4. Exit the Memory Mode

After reaching the last set of result, the meter will display "OFF" and turn off. Anytime in the memory mode, you can press and hold M BUTTON for 3 seconds to turn off the meter.

### Deleting Memory

Press SET BUTTON. The deleting symbol "DEL" appears on the display which confirms that the selected test result has been deleted successfully

## 6. Caring For Your Meter And Test Strip

To avoid the meter and test strips getting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use.

### Cleaning

Your meter does not require special maintenance. As long as no blood or control solution comes in direct contact with the meter, there is no special cleaning required.

To clean the meter exterior, wipe with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft and dry cloth. Do not flush with water.

Do not use organic solvents to clean the meter. Your meter is a precision instrument. Please handle it with care.

### Storage

#### 1. Meter Storage

- Storage condition: -20°C~50°C (-4°F~122°F), below 90% relative humidity.
- Avoid dropping and strong impact.
- Avoid direct sunlight and humidity.

#### 2. Strip Storage

- Storage condition: 4°C~30°C (39°F~86°F), below 90% relative humidity. Do not freeze.
- Store your test strips in their original vial only. Do not transfer to other container.
- Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately replace the vial cap and close it tightly.
- You may touch the test strip anywhere with clean, dry hands when removing it from the vial or inserting it into the meter.
- Use each test strip immediately after removing it from the vial.
- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap and the test strip can be a potential choking hazard. If swallowed, please seek medical assistance immediately.

#### 2. Control Solution

- Please keep in accordance with the Storage/conditions
- Do not freeze

## 7. System Specifications

Product Name	ACEZIN HIGold Blood Glucose and Ketone Meter
Model No.	AM100 PD / AM100 PD-B
Battery	2*CR2032
Operating environment	Temperature: 10°C~40°C (50°F~104°F) Humidity: ≤ 80% R.H.
Storage/ Transport environment	Meter: Temperature: -20°C~50°C / Humidity: ≤90% R.H. Test Strip: Temperature: 4°C~30°C / Humidity: ≤ 90% R.H. Control Solution: Temperature: 2°C~30°C / Humidity: ≤ 90% R.H. Meter: 5 years
Product Life	Test Strip: Shelf life: 24 months; Shelf life after opening: 180 days (Below 30°C) Control: Shelf life: 24 months; Shelf life after opening: 90 days (Below 30°C)
Response	5 seconds
Measurement range	10~600 mg/dl (0.5~33.3 mmol/l)
Hematocrit Range	0%~70%
Memory mode (Sets)	1000 sets
Blood Volume	0.85 µl
LCD Dimension	32 x 41.2 mm
Device Dimension	82 mm (L) x 45 mm (W) x 15 mm (H)
Weight	39 ± 3 g (Without Batteries)

## 8. Display Messages And Problem-Solving Guide

The following is a summary of some display messages and symbols. These messages help to identify certain problems but do not appear in all cases when a problem has occurred.

Improper use may cause an inaccurate result without producing an error message. In the event of a problem, refer to information under "action to take".

DISPLAY	DESCRIPTION	ACTION TO TAKE
	Display check	If some parts of the display are not working. Contact your local distributor for help.
	"Er 1" appears when the strip is wet.	Perform the test in a room around 10 °C ~ 40 °C, and R.H. ≤ 80 %. Repeat the test with a new Test Strip.
	"Er 2" appears when the meter parameter is abnormal.	If "Er 2" appears constantly, please call Ace Medical Technology Co., Ltd. or authorized distributor in business hours.
	"Er 3" appears when your Test Strip does not have enough blood sample on it.	Repeat the test with a new Test Strip.
	"Er 4" appears when the test strip is wrong.	If "Er 4" appears constantly, please call Ace Medical Technology Co., Ltd. or authorized distributor in business hours.
	Glucose test result is higher than 600 mg/dL (33.3 mmol/L).	High or low blood glucose levels can indicate a possibly serious medical condition. If this is not confirmed by the way you feel, review proper testing procedure and perform a control test. Repeat blood test, if the display still appears, please call medical assistance immediately.

	Glucose test result is lower than 10 mg/dL (0.5 mmol/L).	High or low blood glucose levels can indicate a possibly serious medical condition. If this is not confirmed by the way you feel, review proper testing procedure and perform a control test. Repeat blood test, if the display still appears, please call medical assistance immediately.
	Your batteries are about to run out.	Replace battery now.
	The batteries are too weak to work.	Replace battery now.
	Temperature is below the operating range.	The meter is not working. Move to an area with temperature between 10°C to 40°C (50°F ~ 104°F) and wait at least 30 minutes. Do not artificially heat or cool the meter.
	Temperature is above the operating range.	
No responses when the test strip is inserted into the meter.	Maybe: 1. Battery is dead. 2. Wrong test strip is inserted. Meter is defective.	You have to: 1. Replace battery 2. Insert the test strip correctly. 3. Contact your local distributor for help if the problem persists.
No responses when blood sample is applied to the test strip.	Maybe: 1. Blood sample is not sufficient. 2. Meter is defective.	You have to: 1. Repeat test with sufficient sample. 2. Contact your local distributor for help if the problem persists.

## 9. Transmission

### 1. Wired transmission

When the meter is connected to the computer via the USB cable, the LCD displays USB.

USB

When the data starts to be transmitted, the LCD will display PC, indicating that the meter is transmitting the measurement data to the computer.

PC

When the transmission line is unplugged, the Meter displays OFF for 2 seconds and automatically shuts down.

OFF

### 2. Wireless transmission

PRESS M BUTTON 6 second to enter wireless transmission mode.



When the wireless transmission function is turned on, the antenna symbol will be displayed. If the meter is not connected to Apps, the antenna symbol will flash. When the connection is successful, the antenna symbol is always on.

BLE

When the meter and Apps are transferring data, the PC symbol will be displayed. After the transmission is over, the Meter will automatically turn off.

PC