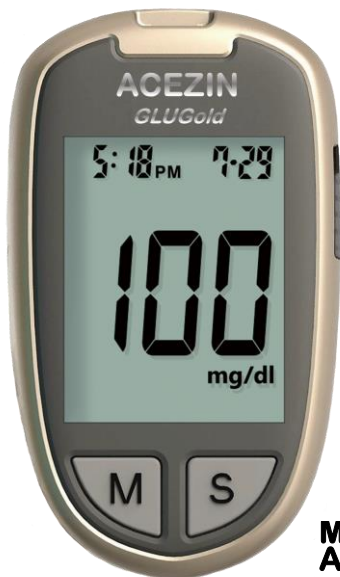


# User's Manual

## ACEZIN *GLUGlod*

### Blood Glucose Monitoring System



**Model No.  
AM100 plus**



## Message to Our Dear User

This booklet has important information you must know about ACEZIN *GLUGold* AM100 plus Blood Glucose Monitoring System with detailed directions and illustrations.


















- ✎ To ensure that you use properly and obtain the best test results possible, please read the entire User's Manual before testing.
- ✎ This package contains 2 new AAA alkaline batteries. Insert them into AM100 plus Blood Glucose Monitoring System by following steps in this manual to ensure normal function.
- ✎ Any concerns? Or need any assistance about maintenance? Please call our Ace Medical Technology Co., Ltd. office or authorized distributor during business hours.

# Caution

- ⚠ To make sure that you operate AM100 plus Blood Glucose Monitoring System safely and accurately, please follow the user's manual.
- ⚠ Please keep AM100 plus Blood Glucose Monitoring System away from any liquid or sprays, keep them dry.
- ⚠ Do not use AM100 plus Blood Glucose Monitoring System on purposes outside "Intended Use".
- ⚠ Only use accessories supplied or recommended by the manufacturer.
- ⚠ Avoid severe impact on the meter. It may cause malfunction.
- ⚠ Do not take AM100 plus Blood Glucose Meter apart, or modify anything. Such action may void your warranty.
- ⚠ Do not place anything on top of AM100 plus Blood Glucose Meter.
- ⚠ Keep the whole AM100 plus Blood Glucose Monitoring System away from children. They may choke on battery, or tiny component parts by accident.
- ⚠ Keep AM100 plus Blood Glucose Meter free from dust, hair, etc. Store the meter in its container after use.
- ⚠ If you feel you are suffering from severe dehydration, stop using and consult healthcare professionals right away.
- ⚠ 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.
- ⚠ Dispose of medical waste per local regulations.
- ⚠ 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.

# Appendices

## Explanation of Symbols

	Caution!
	Authorized representative in the European Community
	This product meets the requirements of Directive 98/79/EC <i>in vitro</i> diagnostic medical devices
	Consult instructions for use
	<i>In vitro</i> diagnostic medical device
	Use-by date
	Manufacturer
	Date of manufacture
	Temperature limit
	Humidity limitation
	Keep away from sunlight
	Do not re-use
	Batch code
	Catalogue number
	2 AAA (1.5 V) Alkaline Batteries
	Biological Risks
	Discard the used product to the recycling collection point according to local regulations

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# About AM100 plus SMBG System

Thank you for choosing AM100 plus Blood Glucose Monitoring System. Designed for ease of use, the device can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

## ***Important Information!***

Expected Results for Non-Diabetic, Non-Pregnant Adults:

The normal fasting glucose range is 70 ~ 100 mg/dl (3.9 ~ 5.6 mmol/l).

Two hours after meals, normal glucose values should be less than 140 mg/dl (7.8 mmol/l).

Severe dehydration resulting from excessive water loss may cause false results. If you feel you are suffering from severe dehydration, consult the healthcare professionals immediately.

- ◆ Test results below 70 mg/dl (3.9 mmol/l) mean low blood glucose (hypoglycemia).
  - ◆ Test results greater than 240 mg/dl (13.3 mmol/l) mean high blood glucose (hyperglycemia).
  - ◆ If you get results below 70 mg/dl (3.9 mmol/l) or above 240 mg/dl (13.3 mmol/l), and do not have symptoms, repeat the test.
  - ◆ If you have symptoms or continue to get results that fall below 70 mg/dl (3.9 mmol/l) or above 240 mg/dl (13.3 mmol/l), follow the treatment advice of your healthcare professional.
- 
- Record the opening date of test strips on its vial. Discard all unused strips 90 days after opening date. The strips are for single use only.
  - 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.
  - Warning of 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.

# About AM100 plus SMBG System

## ***Intended Use***

---

ACEZIN *GLUGold* AM100 plus Blood Glucose Monitoring System is self-test medical device and intended for home testing to monitor the blood glucose ( $\beta$ -D-glucose) levels in fresh capillary whole blood from fingertip and venous whole blood. ACEZIN *GLUGold* AM100 plus Blood Glucose Monitoring System is for In-vitro use only.

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. The owner can only use AM100 plus Blood Glucose Meter with AMG011 Blood Glucose Test Strips.

## ***Measuring Principle***

---

We design AM100 plus Blood Glucose Monitoring System by using the latest biosensor technology. 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”.

The system consists of three main products: AM100 plus Blood Glucose Meter, AMG011 Blood Glucose Test Strips, and ACEZIN *GLUGold* Control Solution. These products have been designed, tested, and proven to work together and perform accurate results.

### ***Note***

The accuracy of AM100 plus Blood Glucose Monitoring System was compared with YSI 2300 Analyzer.



# About AM100 plus SMBG System

## *System Kit*

---

- AM100 plus Blood Glucose Meter
- AMG011 Blood Glucose Test Strips (Sold separately)
- ACEZIN *GLUGold* Control Solution (Sold separately)
- Lancing Device
- 50 Lancets
- AAA (1.5 V) Alkaline Battery x 2
- Pouch
- Complete instructions:
  1. User's Manual for AM100 plus Blood Glucose Monitoring System
  2. Quick Reference Guide
  3. Logbook

### *Note*

- Please consult your provider/local distributor for extra Blood Glucose Test Strips and Glucose Control Solution pack.
- If contents of your package do not meet the system kit list above, please return the whole package to local distributor.
- “If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.”

# About AM100 plus SMBG System

## Component Description

### AM100 plus Blood Glucose Meter

#### Test Strip Slot

Insert test strip here.

#### LCD Screen

Displays blood glucose results, messages, and glucose results stored in memory.

#### Strip Eject Button

Press to eject the used strip

#### M Button

Press to enter different mode.

#### S Button

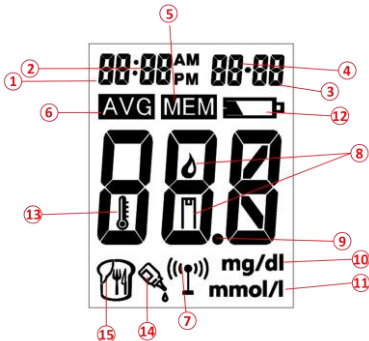
Press to adjust settings and digits



# About AM100 plus SMBG System

## Component Description

### Meter Display



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

# About AM100 plus SMBG System

## *Component Description*

---

### Blood Glucose Test Strips (Sold Separately)



#### *Contact Electrode*

Insert into the test strip slot.

Insert the test strip as far as it will go.

#### *Top Edge (Collection Zone)*

Move blood sample or glucose control solution close to the top edge of the test strip.

---

### **WARNING**

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Keep the strip vial away from children; in case any choking hazard happens. The desiccate reagent in the vial may cause skin or eye irritation by contact.

#### *Note*

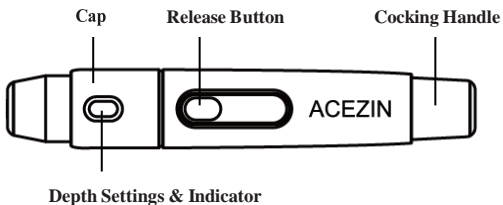
- Only use AMG011 Blood Glucose Test Strips with AM100 plus Blood Glucose Meter only.
- Do not touch the strip when your hands are wet.
- Record the first opening date on the vial, and use them within 90 days after first opening. If not, discard them in case inaccurate results may occur.
- Blood Glucose Test Strips are for single use only. Never reuse.
- Keep Blood Glucose Test Strips in vial always.
- Bending, cutting, or twisting strips are prohibited.
- Read User's Manual for AMG011 Blood Glucose Test Strips for more information.

# About AM100 plus SMBG System

## Component Description

---

### Lancing Device





### Lancets



# Key Features

## *Meal Comment Function*

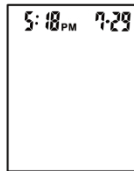
---

Meal Comment Function enables our user to add pre-meal or post-meal symbols on each test result. AC symbol  represents pre-meal results, while PC symbol  represents post-meal results.

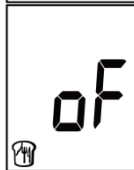
It benefits user to better manage the glucose control plan, also your healthcare professional by providing data when diagnosing and prescribing.

Follow below steps to activate Meal Comment Function:

- 1** Under Standby Mode (Right Figure), press **S** button to enter Meal Comment Setting Mode.







- 2** Our default setting is off (Upper Right). Press **S** button to switch the function on (Lower Right), or off. When done, press **M** button and return to Standby Mode.



## Key Features

### *Note*

- For those who do not wish to change meal comment to test results, simply remove test strip from test strip port after measurement ends. Meter will automatically store your test result in its memory with previous set symbol.
- With Meal Comment Function on:  
Pre-meal: Test result appears with Symbol .  
Post-meal: Our default setting. Test result appears with Symbol .
- When measurement ends, users can press and hold the S button for 1 second, then waiting to hear a “beep” sound while LCD displaying the  or  Symbol, depending on their physical status.

### *Eject Strip Design*


AM100 plus meter features it's eject strip function, which provides user can take out the used strip by pushing and slide the strip eject button after taking measurement.



# Get Ready for Testing

To avoid inaccurate results caused by electromagnetic interference between electrical and electronic equipment, do not use the device near a mobile phone or microwave oven.

## **Battery Installation**

The meter uses 2 pieces of AAA alkaline battery as power source. For new users, please insert 2 new batteries before use, and please replace old batteries with new ones when Low Battery Symbol  shows up.



Slide battery cover from back of meter.




Install 2 new AAA alkaline batteries in accordance with correct polarities.



Put the battery cap back.

### **Note**

- Flashing  Symbol means the battery power is too low to work.
- Past results in storage are intact after battery replacement.
- After battery replacement, please reset year, date and time.
- Do not mix new and old batteries.
- To save the power, please take batteries out if you do not use the meter for a long period (approx. 2 months or more).



# Get Ready for Testing

## Presetting Date/ Time/ Unit

Please pre-set your meter whenever you insert or replace the batteries. See following steps for details.

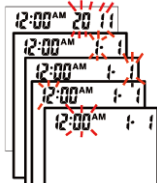
**1**



Under Standby Mode, press and hold **M** button for 3 seconds to enter Setting Mode.

Note: After battery replacement, meter automatically activates Setting Mode.

**2**



When YEAR digits flash, press **S** button to select current year. When done, press **M** button to confirm.

To complete date and time settings, repeat above steps by setting MONTH, DATE, HOUR and MINUTE in sequence.

**3**



After setting the correct year, select preferable unit by pressing **S** button. When done, press **M** button to confirm.

# Quality Control of the System

## *Using Glucose Control Solution (Sold Separately)*

The purpose of ACEZIN *GLUGold* Control Solution is to perform a quality control test to verify whether your meter and test strips are working together properly.

There are two levels of Glucose Control Solutions for different acceptable ranges: High Level and Medium Level. We recommend testing with both levels of Glucose Control Solution.

### • How does it work?

A known amount of glucose in the control solution reacts with AMG011 Blood Glucose Test Strip.

### • Who or when to perform a control solution test?


- Handling your meter at the first time.
- After opening a new vial of test strips.
- Strong impact on the meter.
- When your symptoms do not agree with the way you feel, or when the result is higher or lower than expectation.
- Whenever users wish to check whether Blood Glucose Test Strip and Blood Glucose Meter are working properly.


### *Note*

- For accurate results on both blood glucose measurements and quality control tests, use ACEZIN *GLUGold* Control Solution only.
- Results of quality control tests will not be stored in the memory.

**1** Insert test strip into test strip slot.



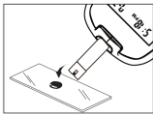
**2** When  symbol flashes, press **S** button to activate Quality Control Mode.

With  symbol on, your meter is ready to perform quality control test.



# Quality Control of the System

- 3** Shake the vial of Glucose Control Solution well before use. Squeeze the vial but discard the first droplet.



Squeeze the second droplet to your clean fingertip or on a clean object such as a transparency.

Move the collection zone of test strip close to Glucose Control Solution droplet. Collection zone automatically drinks the droplet in. When full, your meter beeps and counts down for 5 seconds.

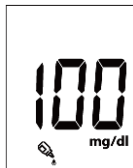
## NOTE

To avoid contamination, do not apply the control solution to the test strip directly from the bottle.

- 4** When results match with acceptable range printed on the Test Strip vial, your System is working properly.

## Note

Check the Test Strip vial for acceptable ranges for High and Medium Levels. Refer to Glucose Control Solution instruction before use.



## Understanding Your Test Results

When results match with acceptable range printed on the Test Strip vial, your System is working properly, and your test results are reliable.

If your results do not match with the acceptable range, please check the following:

- Are the control solutions or test strips within the expiration date?
- Has the control solution been contaminated?
- Did you follow the test procedures correctly?

*Please repeat the test. If results still do not match, contact your local Ace Medical office or the authorized distributor.*

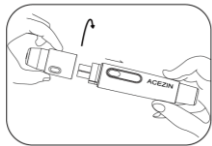
# Perform the Blood Glucose Test

## Perform the Blood Glucose Test

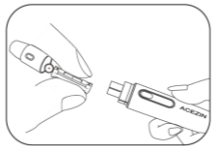
### CAUTION

- To avoid infection, do not share the lancing device and lancets with other people. The lancet is for single use only. Never reuse them.
- Be sure to save the protective cap of the lancet for later use. Remember to put it back on to the lancet before disposal.
- When **LOt** or **Ht** appears, ambient temperature falls out of acceptable range (10 °C ~ 40 °C / 50 °F ~ 104 °F). Leave your meter in a room around 10 °C ~ 40 °C (50 °F ~ 104 °F) for 15 minutes, then repeat the test. Do not artificially heat or cool the meter.
- The strip is for single use only. Dispose of Test Strip that has blood or control solution on it.

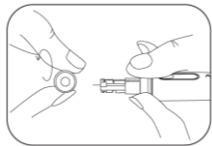
- 1** Twist the cap of the lancing device to remove it.



- 2** Insert the lancet firmly into the circular lancet holder of lancing device until it is fully seated.

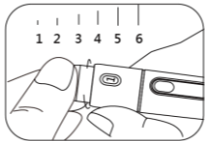


- 3** Twist off the protective cap of the lancet and save it for later use.

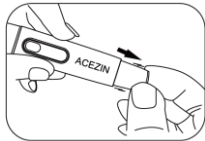


# Perform the Blood Glucose Test

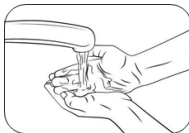
- 4** Replace and screw the cap snugly. Choose the depth of lancing. Select 1~2 for soft or thin skin, 3~4 for average skin, 5~6 for thick or calloused skin.



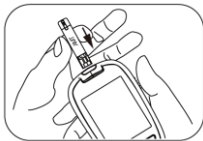
- 5** Pull the cocking handle out until it clicks.



- 6** Wash hands first, or use an alcohol swab to wipe your finger clean. Wait until your hands are totally dry.



- 7** Insert the test strip into the test strip slot as the figure on the right.

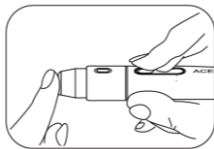


## **Note**

The meter does not response to any other ways of inserting


## Perform the Blood Glucose Test

- 8** Hold the lancing device firmly against the side of your finger tip.  
Let go of the Release Button to take a sample.



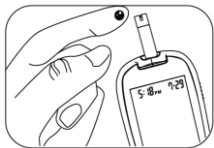
- 9** To avoid body fluid contamination, wipe off the first drop of blood with a clean gauze or cotton. Gently squeeze the fingertip to obtain the second drop of blood for testing.



- 10** With  symbol on, your meter is ready for use.



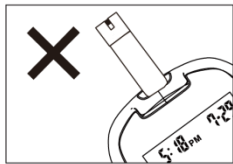
- 11** Move the collection zone close to your finger tip. Do not drip your blood sample on the top of the test strip.



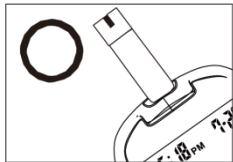
# Perform the Blood Glucose Test

## NOTICE

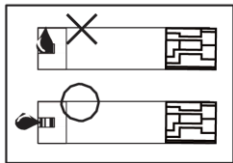
Make sure to apply enough blood on the collection zone of the Test Strip. An unfilled collection zone may lead to false or inaccurate result.



Your Test Strip doesn't have enough blood sample on it. An unfilled collection zone may lead to false or inaccurate result.



A totally filled collection zone.



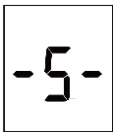
Do not drip your blood sample on the top of the test strip.

Instead, move the test strip close to blood sample, and let collection zone automatically drink the droplet in.

## Perform the Blood Glucose Test



**12** Meter beeps when blood is detected, and user can then move your finger away.

**13** Glucose test result displays in 5 seconds.





**14** The result is shown on the display.



**15** With Meal Comment Function on, test result appears with flashing  or  symbol, depending on the setting.



### Note

User can replace  or  Symbol by pressing and holding **S** button for 1 second and waiting to hear a “beep” sound, depending on their physical status.

Pre-meal: Test result appears with Symbol .

Post-meal: Our default setting. Test result appears with Symbol .

**16** 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.

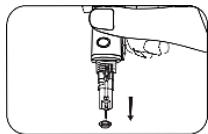
Without any operation for 2 minutes, the meter automatically shuts off too.





# Perform the Blood Glucose Test

- After testing, push the lancet ejector forward to remove the lancet. Be sure to put protective cap of the lancet back before disposal.
- Dispose of medical waste per local regulations.



## LO and HI Readings

AM100 plus Blood Glucose Monitoring System can display results from 20 to 600 mg/dl (1.1 to 33.3 mmol/l).

1. If your test result is lower than 20 mg/dl (1.1 mmol/l), “LO” appears on LCD screen. The result will be stored in the memory but does not count in the average of last 7/ 14/ 30/ 60 days.

### *Important information!*

#### ➤ **LO reading with symptoms!**

If you have “LO” test results and also symptoms such as weakness, sweating, nervousness, headache or confusion, follow your doctor’s recommendation to treat hypoglycemia.

#### ➤ **LO reading without symptoms!**

If you have “LO” test results but no symptoms of low blood glucose, please consult your doctor or call your local distributor for help.

2. If your test result is higher than 600 mg/dl (33.3 mmol/l), “HI” appears on LCD screen. The result will be stored in the memory but does not count in the average of last 7/ 14/ 30/ 60 days.

### *Important information!*

#### ➤ **HI reading with symptoms!**

If you have “HI” test results and also symptoms such as fatigue, thirst, excess urination, or blurry vision, follow your doctor’s recommendation to treat hyperglycemia.

#### ➤ **HI reading without symptoms!**



If you have “HI” test results but no symptoms of high blood glucose, please consult your doctor or call your local distributor for help.

# Perform the Blood Glucose Test

## Memory Recall

AM100 plus Blood Glucose Meter can store up to 1000 test results with date and time automatically in its memory. When full, the meter will replace the oldest with the latest result automatically. User can also view their average results of last 7/ 14/ 30/ 60 days with ease.

### Note

1. To ensure accurate average values, please re-set date and time before use.
2. Average result of last 7/ 14/ 30/ 60 days is calculated from test results performed during the last 7/ 14/ 30/ 60 days.
3. “LO” and “HI” results do not count in the average of last 7/ 14/ 30/ 60 days.
4. With Meal Comment Function on, Pre-meal  or Post-meal  Symbol will also appear under Memory Mode.

Follow steps below to recall memory sets:

- 1 Under Standby Mode, press **M** button to enter Memory Mode.

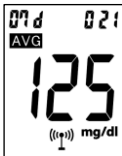
### Note

To quit Memory Mode, press **S** button and return to Standby Mode.

- 2 Average result of last 7 days appears first.

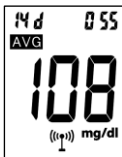
## Understanding Average Results

Take average of last 7 days for example. While displaying average results, “07d” on the upper left represents the result displaying now are from last 7 days. “021” on the upper right represents how many results are performed during last 7 days. The indications apply to the following figures of 7/14/30/60 days average.

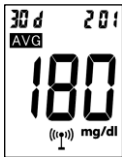


# Perform the Blood Glucose Test

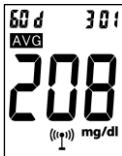
**3** Press M button again to view the average record for last 14 days.



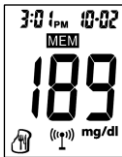
**4** Press M button again to view the average record for last 30 days.



**5** Press M button again to view the average record for last 60 days.



**6** To view the records in the memory: press M button again, the meter start displaying each test result with memory sequence number, and then corresponding date and time.



Keep pressing M button, user can scroll through all memory sets from the latest to the oldest.

## Note

- To fast scroll forward, press and hold **M** button.
- To leave the Memory Mode, press **S** button for 2 seconds and the meter switches to Standby Mode.

# Perform the Blood Glucose Test

## *To delete all records*

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- 1** Press **S** and **M** buttons for 3 seconds, the screen will show "dA" for confirmation.
- 2** Press **S** button again for 3 seconds to delete all records.

Or if you want to check out the delete function, press **M** button to return to Standby Mode.





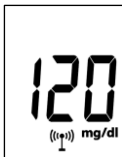
### *Note*

**Once deleted, your data can NOT be restored.**

# Perform the Blood Glucose Test

## Wireless Transmission

- 1** To activate Wireless Transmission function, please make sure your Wireless Transmission device have downloaded APP, and follow pairing instruction.
- 2** Once the meter is on, the Wireless Transmission will broadcast with “” symbol shows up. When connect and data transmit to Wireless Transmission device, the screen flashes “” symbol. Please make sure the meter and Wireless Transmission device are in 5 meters.
- 3** AM100 plus can only pair up with one Wireless Transmission device at a time. To transmit measuring results to other Wireless Transmission device, please redo steps 1~2.



**Note:** Please do not turn on more than one Wireless transmission function of glucose meters.

- ◆ AM100 plus is subject to and complies with electromagnetic compatibility (EMC) standard of IEC 60601-1-2, EN 301 489-1, EN 301 489-17, EN 300 328 and U.S. federal guidelines, Part 15 of the FCC (Federal Communications Commission) rules for devices with RF capability. These guidelines help ensure that your device will not affect the operation of other nearby devices. Additionally, other devices should not affect the use of your device.
- ◆ Make sure AM100 plus and paired Wireless transmission device are within acceptable distance (no more than 10 meters) with each other. If not, put them closer.

# Perform the Blood Glucose Test

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.*

# Maintain Your Meter

## 1 Display Check

When the meter is off, press any key to switch it on. The display should look exactly like the figure in the right.

If not, call Customer Service of Ace Medical Technology Co., Ltd.



## 2 Storage and Handling

Keep your meter free from dust, and extreme weather. Always handle your meter with care.

Run a quality control test after strong impact of the meter.

### *Important Information*

- ⚠ Watch out for ingress of water while wiping Test Strip Slot.
- ⚠ Do not dip your meter in water, or any other liquid.

## *Cleaning the Meter*

Keep the meter free of dust. If you need to clean or disinfect it, follow these guidelines carefully to help you get the best performance possible.

1 Make sure the meter is turned off.

2 Gently wipe the meter's surface with a soft cloth slightly dampened (wiping out any excess liquid) with one of these cleaning solutions:

- 70 % isopropyl alcohol
- 10 % household bleach solution (1 part bleach plus 9 parts water) made the same day

### *Warning*

- Do not allow liquid to enter any openings in the meter.
- Do not spray a cleaning solution directly onto the meter.
- Do not immerse the meter in liquid.

# System Specifications

## Limitations

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- 1** Do NOT use neonate blood sample.
- 2** Blood Glucose Test Strips are for single use only.  
Never reuse a test strip that had either blood or control solution applied to it.
- 3** Use AM100 plus Blood Glucose Monitoring System at room temperature between 10 °C ~ 40 °C (50 °F ~ 104 °F). Out of this range, the device just won't work.
- 4** Extreme humidity may affect the results. A relative humidity greater than 80% may cause incorrect results.
- 5** Hematocrit:
  - ✎ Hematocrit ranging from 0 % ~ 70 % has no significant impact on test results.
  - ✎ Other ranges:  
Hematocrit > 70 %: may lead to incorrect low test results.
  - ✎ To know exact hematocrit level of yours, consult healthcare professional for help.



# System Specifications

## Product Specifications




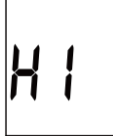

<b>Product Name:</b>	AceZin <i>GLUGold</i> blood glucose meter	
<b>Model No.:</b>	AM100 plus	
<b>Range</b>	20 ~ 600 mg/dl (1.1 ~ 33.3 mmol/l)	
<b>Response time</b>	5 seconds	
<b>Memory sets</b>	1000 Memory Sets	
<b>Operating Condition</b>	Temperature	10 °C ~ 40 °C (50 °F ~ 104 °F)
	Humidity	R.H. ≤ 80 %
<b>Storage Condition</b>	Meter	-40 °C ~ 55 °C (-40 °F ~ 131 °F) R.H. ≤ 90 %
	Strip	4 °C ~ 30 °C (39.2 °F ~ 86 °F) R.H. ≤ 90 %
<b>Transportation Condition</b>	Meter	-40 °C ~ 55 °C (-40 °F ~ 131 °F) R.H. ≤ 90 %
	Package with Strips	4 °C ~ 30 °C (39.2 °F ~ 86 °F) R.H. ≤ 90 %
<b>Blood Volume</b>	> 1.0 µl	
<b>Sample Type</b>	Capillary whole blood from fingertip and venous whole blood	
<b>Hematocrit (Hct)</b>	0% ~ 70%	
<b>Power Supply</b>	AAA (1.5 V) Alkaline Battery x 2	
<b>Battery Life</b>	1000 measurements	
<b>LCD Dimension</b>	40 x 29 mm	
<b>Device Dimension</b>	100 mm (L) x 60 mm (W) x 23 mm (H)	
<b>Weight</b>	63 ± 3 g (Without Batteries)	
<b>Principles</b>	Electrochemical Biosensor Technology	

# System Specifications

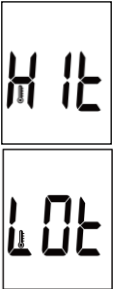
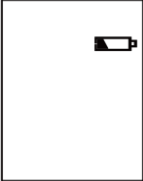


## Wireless Transmission Specifications

RF Type	5.0 BLE
RF Modulation	GFSK
Effective Radiated Power	3.99 dBm
Data Throughput	1Mbps
Expected Delay (Latency Range) in Wireless (RF) Communication	The latency time is less than 0.3ms second from sender to receiver.
Integrity	Channel Quality-Driven Data Rate (CQDDR) technology increases the effective data rate and integrity in noisy environments.
Security	AES-128 and application layer user defined
Operating Distance	Class 2 (Maximum: 10 meter))
RF Frequency / Need for Spectrum Management	2402 - 2480 MHz (allowing for guard bands)
Maximum Limitation	Unlimited
Maximum Permitted Power	0.47 mW
Proximity of Other In-band Transmitters Used in Vicinity	up to 40 bands (2 MHz spacing; centered from 2402 to 2480 MHz)
Wireless Communication Profile	GATT – Client and Server
Wireless Coexistence	Support for 802.11 Coexistence

# Display Messages and Troubleshooting

Display messages	What it means	Troubleshooting
	<p>"Er 1" appears when the strip is wet.</p>	<ul style="list-style-type: none"> <li>➤ Perform the test in a room around 10 °C ~ 40 °C, and R.H. ≤ 80 %.</li> <li>➤ Repeat the test with a new Test Strip.</li> <li>➤ See "Perform the Glucose Blood Test" section.</li> </ul>
	<p>"Er 2" appears when the meter fails to access memory.</p>	<p>If "Er 2" appears constantly, please call Ace Medical Technology Co., Ltd. or authorized distributor in business hours.</p>
	<p>"Er 3" appears when your Test Strip does not have enough blood sample on it.</p>	<ul style="list-style-type: none"> <li>➤ Repeat the test with a new Test Strip.</li> <li>➤ See "Perform the Glucose Blood Test" section.</li> </ul>
 	<p>"HI" and "LO" appear when your results fall out of measuring range.</p> <p>The result will be stored in the memory but does not count in the average of last 7/14/30/60 days.</p>	<ul style="list-style-type: none"> <li>➤ Repeat the test with a new Test Strip.</li> <li>➤ See "Perform the Glucose Blood Test" section.</li> </ul>

# Display Messages and Troubleshooting

Display messages	What it means	Troubleshooting
	<p>When “HI t” or “LO t” appears, ambient temperature falls out of acceptable range (10 °C ~ 40 °C / 50 °F ~ 104 °F).</p> <p>The meter is unable to measure.</p>	<ul style="list-style-type: none"> <li>➤ Do not artificially heat or cool the meter.</li> <li>➤ Leave your meter in a room around 10 °C ~ 40 °C (50 °F ~ 104 °F) for 15 minutes, then repeat the test.</li> <li>➤ See "Perform the Glucose Blood Test" section.</li> </ul>
	<p>When  appears, your batteries are about to run out.</p> <p>When  appears, the batteries are too weak to work.</p>	<ul style="list-style-type: none"> <li>➤ Repeat the test after battery replacement.</li> <li>➤ See "Get Ready for Testing" section.</li> </ul>

# Device Information

## *AM100 plus Blood Glucose Monitoring System*

AM100 plus Blood Glucose Meter

AMG011 Blood Glucose Test Strips

ACEZIN *GLUGold* Glucose Control Solution

ACEZIN Lancing Device

ACEZIN Lancets



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EC

REP

**MedNet EC-REP GmbH**

Borkstraße 10, 48163 Münster, Germany

# Device Information

## *Lancing Device*

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Meets the requirement of MDD 93/42/EEC



### **Medifun Corporation**

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<http://www.medifuncorp.com>

## *Lancets*

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Meets the requirement of MDD 93/42/EEC



### **Tianjin Huahong Technology Co., Ltd**

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Tel: +86-022-58775333

<http://en.huahong-technology.com>

## Device Information

### *Warranty*

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Ace Medical Technology Co., Ltd. warrants that your ACEZIN *GLUGold* AM100 plus Blood Glucose Meter will be free from defects in materials and workmanship for one year from the date of purchase. If during this one-year period, the meter does not work properly because of a defect in materials or workmanship, Ace Medical Technology Co., Ltd. SERVICE will repair the meter or replace it with a new ACEZIN *GLUGold* AM100 plus Blood Glucose Meter or equivalent product free of charge.

The warranty of the repaired or replacement meter will expire on the date of the original warranty expiration or ninety days after shipment of a replacement meter, whichever period is longer.

### *Note*

This warranty applies only to the original purchaser of the meter.

