

Ecare IA Blood Glucose Monitoring System User's Manual



For Model : GM20E

Intended for use

The **Ecare IA** Blood Glucose Monitoring Systems is intended for the quantitative measurement of glucose in fresh venous whole blood, or in fresh capillary whole blood from the fingertip. It is intended people with diabetes mellitus at home or healthcare facilities for monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Test Principle

The **Ecare IA** blood glucose monitoring system is plasma calibrated to allow easy comparison of results with laboratory methods. Glucose in the blood sample mixes with special chemicals on the test strip and a small electrical current is produced. This current is measured by the **Ecare IA** Meter and displayed as your blood glucose result. The strength of these currents changes with the amount of glucose in the blood sample.

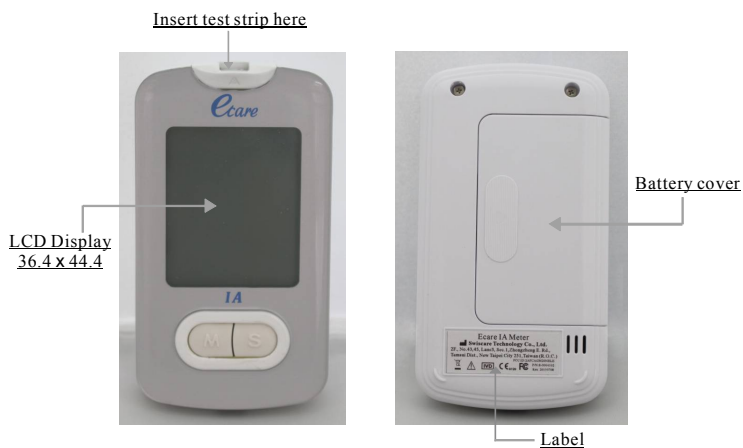
IVD This device is an in vitro diagnostic medical device.

Do not use the meter for diagnosing diabetes.

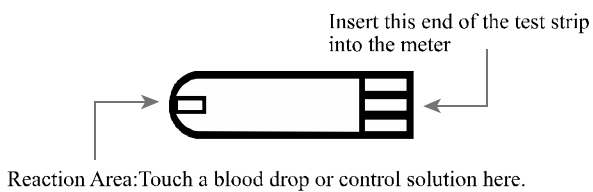
⚠ Do not change the treatment based on a single result which doesn't match how you feel or if you believe your test result is incorrect.

- If the test result does not match how you feel and you have followed the instruction in the manual, please consult your doctor.
- The severe dehydration or water lost might cause the false result .
- Please talk to your doctor if you are sure to have water loss.
- Please do not take a measurement near the mobile or the microwave oven, or it might lead to the incorrect result.
- Run a control test by Ecare GDH Control Material (optional accessory) when you open a new vial of test strips or if you think that your test result is incorrect. Running a control test lets you know that the meter and test strips are working properly.

Know your meter



Ecare IA Blood Glucose Test strip

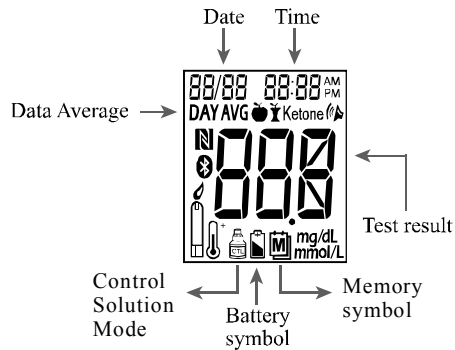


Note
1. **Ecare IA** Meter should only be used with **Ecare IA** Blood Glucose Test Strip. Using other test strips with this meter can produce inaccurate results.
2. The front side of the **Ecare IA** Blood Glucose Test Strip should face up when inserting the **Ecare IA** Blood Glucose Test Strip.
3. The strips are for single use only, please do not reuse or use the used strip and repeat the test.

Product & accessories

1. Ecare IA Meter × 1 .Lancet device × 1
 3. Ecare IA Blood Glucose Test Strip vial × 1
 4. Lancet × 10
 5. Ecare GDH Control Material (Optional)
 6. AAA Alkaline Battery
- Please purchase a extra strip box from our distributor, just in case of running out of the strips .

LCD display

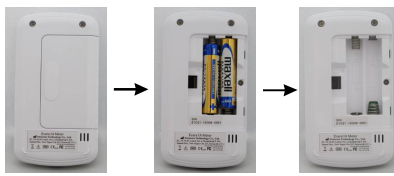


Explanation of LCD display

- Please insert the test strip
- The temperature is out of range
- Please apply blood to the strip
- Control solution mode
- Measurement Unit
mg/dL Milligram per Deciliter
mmol/L Millimole per Liter

Battery installation

- This meter has been installed 2 × AAA battery.
 - Please do not use the defective or the expired battery, it might lead to cause false result.
 - Before replacing the batteries, please turn the meter off.
1. Press the battery cover and push forward with your thumb slightly .
 2. Remove the battery cover.
 3. Replace the old batteries with the new ones and match the polarities.



LCD symbol: Battery power

When low power symbol appears on the display, it reminds the user that there are 20 times usages and can prepare the battery in advance.



First time use setting

1. Press S button 2 seconds into the setting mode. (no test strip inserted). Please follow the below steps to change the parameters. **Setting Mode**
2. The "L-1" on the display. Press "M" to select the languages(L-1~L-3) ,then press "S" to confirm language: L-1 → L-3
3. The "3" on the display. Press "M" to select the volume(3~0) , then press "S" to confirm volume: 3:high volume 0:mute -3- → -0-

Change the date and time

1. The year flashes on the display. Press "M" to select the year(2015~2050) ,then press "S" to confirm year.
 2. Repeat the same steps to set the month, date ,hour and minute.
- Note**
The hour format is the 12-hour time.

Set the measurement unit

1. The measurement unit flashes.
 2. Set the measurement unit: Press "M" to select the unit :mg/dL or mmol/L.
 3. Press "S" to confirm measurement unit.
- Note**
1. The unit can be changed in setting mode.
2. If you can not change unit during step 2, it means the system was fixed the unit by default setting.

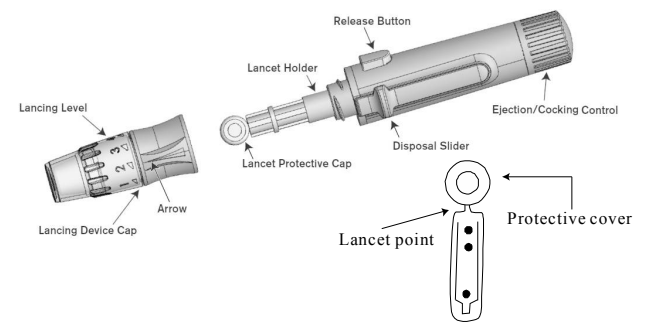
Delete the test result

1. The "dEL" display, press "S" goes to sleep mode.
2. Or press "M" 2 sec, it displays "OK" to delete all memory, then goes to sleep mode.

Preparing the test strip

1. Wash hands with soap and warm water. Rinse and dry thoroughly.
2. Pull out a test strip from the box and **must re-cap the box immediately.**
3. Insert the test strip, the front side of the test strip face up, into the test port. The meter will automatically turn on.

Operation of Lancing device



1. Twist off the Lancet Device Cap.
2. Insert the lancet and remove the cap of the lancet device.
3. Twist the protective cover of the lancet, snap the cap back on.
4. Twist the Adjustable Tip in either direction until the numbers line up with the Arrow.

Depth of lancet device
1-2: For children and adolescent , thick skin with no corns.
3-4 :For women and mid-aged people or the elderly.
5 :Thick skin with corns, for mid-aged people or the elderly.

Preparing your blood sample

1. Wash your hands with soap and warm water. Then rinse and dry thoroughly.
2. Massage the puncture site.
3. Using lancet device firmly on the side of the fingertip to get a drop of blood.
4. Press the button on the lancet device. The blood has been taking as you hear a click sound.
5. Gently squeeze or massage your finger until drop of blood forms.

Note
• The user must wash hands thoroughly with soap and water after handling the meter, lancet device or test strips.
• The lancets can not to be re-used or used more than one person to increase the infection risk.
• Don't use Povidone Iodine Solution or any org nic solvent for cleaning!
• Wait until hands dry completely!

AST alternate site testing

• Alternative site testing means that people test blood glucose from the forearm, upper arm or finger tip.



- Please consult your doctor to determine if alternative site testing is right for you.
- Select a soft, fleshy area of skin that is free from hair, moles and visible veins for alternative site testing.
- Avoid lancing areas with obvious veins or moles to avoid excess bleeding or where tendons or bones stick out (for example, hand bones and ankle bones)

It is strongly recommend that do AST ONLY in the following intervals
-In a pre-meal or fasting state (more than 2 hours since the last meal).
-Two hours or more after taking insulin.
-Two hours or more after exercise.
Do Not do AST
-You think your blood glucose is low.
-You are unaware of hypoglycemia.
-Your AST results do not match how you feel.
-You are testing for hyperglycemia.
-Your routine glucose results are often fluctuating.
-If you are pregnant.

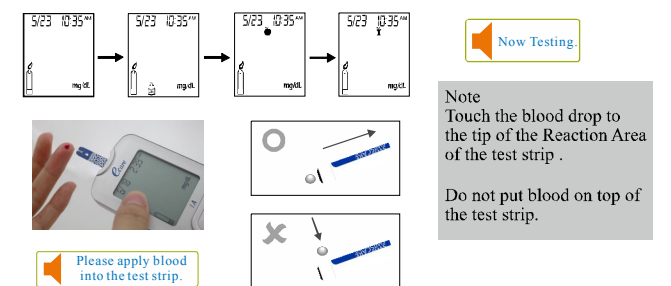
Steps of testing your blood glucose

1. Inserting the test strip.
2. Press "M" button to highlight your status as "control mode", "before meals", "after meals" or in general mode without labeling.

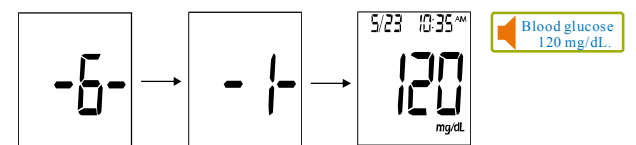


- a) Pressing once "M" button highlights the value with as control solution mode. (Testing results in control solution mode will not store in memory.)
- b) Pressing once "M" button highlights the value with as before meals status.
- c) Pressing once "M" button highlights the value with as after meals status.
- d) Pressing one more "M" button removes the highlight with general mode.

3. Put your blood drop to the Reaction Area on the strip.



4. After dropping the blood , you will hear a beep sound, then it starts 6 seconds count down at the same time.



5. The result will appear on the display, auto-saving in memory.
6. Remove the used test strip, then it goes to sleep mode.

Note
1. Please do not touch on the strip by your finger or use the smearing blood sample.
2. Do not remove the strip before complete 6 seconds count down, or it will be automatically shut down.
3. The test strips cannot be re-used.

Review memory

The meter can store up to 300 test results.

Enter the memory mode

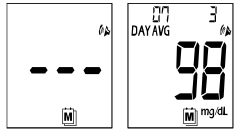
1. Press "M" 2 seconds with the meter off to enter the memory mode.



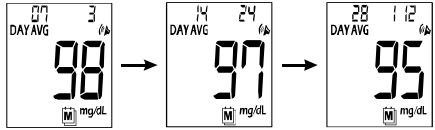
Note

- No result appears when first time using the new Ecare Meter. And appears three dashes on the display.
- You will not be able to perform a blood glucose test in this mode.

2. The first result appears on the display is the 7 days average of the test results, and numbers of the result in 7 days displayed on upper right side.



3. Press "M" continuously, the consecutive 14/28-days average results will be shown on display in order.

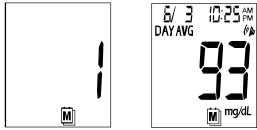


Note

The consecutive 7/14/28-day average is calculated from the blood glucose results obtained during the last consecutive 7/14/28-day.

Review memory

- When "1" appears on the display, the value of the first result will appear later automatically.
- "1" means the most recent result with the result appears on the display.



- Press the "M" button continually to review the results until last one.
- Press the "M" button once, than it will be into the sleep mode and turned off automatically.
- If you do not review memory during step 1~4, press "S" button to turn off the meter.



Transfer data

If you would like to review the results from the computer, please contact the sales distributor for assistance.



If you want to transfer your blood glucose testing data to computer(PC), please transfer your data by using "Ecare BGMs Data Transfer Software". Your blood glucose data shall be automatic transferred successfully by performing following steps:

- Connect one end of the USB Cable to the USB port of your meter.
- Connect the other end of the USB Cable to the USB port of your personal computer(PC).



Guidance for condition

Screen Display	Situation	Action
	1. Connect to the PC by USB cable. 2. Please follow the procedures described in "Ecare BGMs Data Transfer Software".	Date transferring starts connection and will upload successfully automatically.

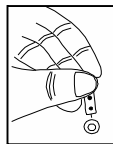
Removing the used lancet

Note

- It is important to dispose the used lancet carefully after each use to minimize the risk of transmitting bloodborne pathogens.
- Please follow your local regulations or ask your doctor for recommended methods of lancet disposal.



- Place the lancet cover on a hard surface. Push the lancet point into the cover.
- Place the lancet cover back on the exposed lancet point.
- Discard the used lancet and test strip.



Storage of strips

- The expiration time of a strip vial is (YYYY-MM).
- Once you open it, the expired time is 90 days.
- It is recommended to write the date when you open the strip vial.
- Please do not use the strip past the expired date which may lead to the wrong result.
- A drying agent is included in the strip vial.
- Please keep the strips and the vial away from the children, prevent them from eating.
- Storage Circumstance:
Meter : -20~70°C (-4~158 °F) RH:10~90%
Strip : 6~42°C (42.8~107.6 °F)
- Keep away from moisture and sunlight.
- Please store the strip vial in a safe and dry location, and avoid long-term sun exposure.
- Do not store the strips outside the vial.
- Do not store the strip in the other vial.
- Please do not touch the strip by a wet hand.
- Once you take the strip from the vial, please use it as soon as possible. And re-cap the vial immediately.
- Please do not bend or cut the strip.

Cleaning and disinfection

- Never immerse the meter or lancet device in water, and do not get any moisture in the test strip slot.
- Do not get wet at the computer port.
- Make sure the meter is off.

1. Wipe the meter or lancet device by following recommended material:

- CaviWipes™ (EPA * reg. no. 46781-8)



Note

Do not use vinegar or scouring agents to clean meter because they can harm the display and measurement window.
* Environmental Protection Agency.



2. Wipe the meter dry with a soft cloth or gauze.



3. CaviWipes™ can be purchased from the following sources:

- Amazon.com
- Officedepot.com
- Walmart.com



Maintenance

- Please store the system in a safe and dry location.
- Avoid long-term sun exposure.
- Avoid the meter to strong shocks, such as dropping the unit on the floor.
- If the meter will not be used every day, please remove the battery.

Warning message

Screen Display	Situation	Action
	Blood glucose testing is higher than 600 mg/dl (33.3mmol/L)	1. Run a control solution test and restart the test.
	Blood glucose testing is lower than 20 mg/dl (1.1mmol/L)	2. If the result of control solution test is in normal range, please test again.
	High blood glucose level, possibly ketones.	
	The "Ketone" flashes 5 seconds and displayed on screen.	
	Operating temperature is above 40°C.	Please operate the meter in the appropriate temperature: 10-40°C (50-104°F)
	Operating temperature is below 10°C.	Please operate the meter in the appropriate temperature: 10-40°C (50-104°F)
	Low battery.	Change the battery.
	USB disconnection when remove the meter or the USB cable during the transfer.	Try again. If the same issue occurs, please ask for help for the local distributors.
	Damaged or used strips.	Damaged or used strip, please discard it and test again.
	Meter internal self-checking error.	Please contact your local distributor.
	Insufficient blood volume.	Please prepare sufficient blood volume and test again by new strip.

Guidance for error condition

Note: Never make treatment decisions based on an error message, if you have any concerns, please contact your distributor.

Screen Display	Situation	Action
	Low battery.	Replace the batteries.
	Wrong Batteries polarities.	Check the battery installation.
	Strip is inserted by the wrong direction.	Check the direction of the strip.
	Malfunctioning meter.	Contact the distributor.
	Not enough blood.	Discard the test strip and test again.
	Defective strip.	
	Malfunctioning meter.	Contact the distributor.
	The temperature of storing the control solution is too low or high.	Equilibrate the control material at room temperature for 30 minutes.
	Do not expose to the sunligh	Do not freeze in a refrigerator.
	The test of control solution is out of the range.	The control solution is expired, damaged from contamination or improper usage Discard it and use a new one. Test again.

Name	Ecare IA Blood Glucose Monitoring System
Battery	2 × AAA Alkaline
Battery Life	Approximately 1,000 tests
Dimension & Weight	97 × 54 × 20 mm & 83 g(with battery)
Measurement Range	20 mg/dl ~ 600 mg/dl (1.1mmol/l ~ 33.3mmol/l)
Operation Temperature	10~40°C (50~104 °F)
Operation Humidity	10~90 %
Storage Circumstance	Meter : -20~70°C (-4~158 °F) Strip : 6~42°C (42.8~107.6F) RH:10~90%
Response Time	6 seconds
Average	7/14/28 days average results
Hematocrit	20%~60 %
Sample Volume	1.0ul
Test Sample	Capillary or Venous whole blood

THE SYMBOL

	Consult operating instructions
	Caution need consult the instruction for use
	Your test strips' lot number
	Serial number
	Use-by date
	For in vitro diagnostic use
	Control Material
	Do not reuse
	Temperature Limitation
	EU Authorized Representative
	Manufacturer

FCC Marking:

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.



NOTE: 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 this 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.



Dispose of used test strip as well as lancets carefully to prevent injury or contamination. Please dispose of in accordance with your local ordinances



For environmental reasons, do not dispose of the device with the household waste at the end of its service life. If you have any questions, please contact the local authorities responsible for waste disposal.

Customer service

If you have any questions or concerns regarding this product or the product issues which can't be solved through trouble shooting tips, please do not assemble by yourself and contact us for assistance.



Customer service line:
+1-949-702-0769, 24 hours a day, 365 days a year.



Swiscare Technology Co., Ltd.
2F., No.43,45, Lane3, Sec.1,Zhongzheng E. Rd.,
Tamsui Dist.,New Taipei City 251, Taiwan (R.O.C.)
TEL : +886-2-2629-0878
FAX : +886-2-2629-0118
E-mail : service@swiscare.com

Lancet

Manufactured by:



Shandong Lianfa Medical Plastic Products Co., Ltd
No.1 Shuangshan Sanjian Road 250200 Zhangqiu City,Jinan,
Shandong PEOPLE'S REPUBLIC CHINA