DiaCheck DA12

Blood Glucose Monitoring System

User Guide

for Self-Testing

Apollo Diagnostics

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A. INTRODUCTION

Thank you for purchasing the DA12 Blood Glucose Monitoring System.

Before using the unit for the first time, please be sure to read this user guide carefully and use the unit safely and properly.

Please keep this user guide at hand all the time for the future reference.

INTENDED USE

They are designed for users to measure the glucose concentration in the capillary and vein obtained from fingertips, palm and forearm. Professionals may use DA12 Blood Glucose Monitoring System to test capillary and vein, but home use only can test the capillary whole blood. DA12 system is intended to be used by lay person with diabetes in home, or professionals use in healthcare facilities.

⚠ Warning: Only the DA12 blood glucose test strips are used with DA12 meter.

⚠ Warning: Only used for in vitro diagnostic.

B. IMPORTANT SAFETY WARNINGS AND CAUTIONS

It is important that user read all the warnings and cautions included in this instruction manual before using the unit because they are intended to keep user safe, prevent injury and avoid a situation that could result in damage to the device.

GENERAL WARNINGS

♦ Before using this device to test blood glucose, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.

♦ The device for self-testing is used for the monitoring of an existing disease (e.g., diabetes), before changing treatment patients should refer to a medical professional.

♦ This device does NOT serve as a cure for any symptoms or diseases. The data measured is for reference only.

♦ User should not take any decision of medical relevance without first consulting a medical practitioner. Always consult user's doctor to have the results interpreted.

♦ Only used for in-vitro diagnostic test.

♦ Please read meter manual and strip manual carefully before using DA12 meter.

♦ Keep this unit from strong impact

♦ Do not disassemble, repair, or remodel the unit.

♦ Keep this unit out of the reach of children.

DO NOT USE THIS UNIT UNDER THESE CONDITIONS

♦ Use this device ONLY for the intended use described in this manual.

♦ Do NOT use accessories which are not specified by the manufacturer.

♦ Do NOT use the device if it is not working properly or if it is damaged.

♦ Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.

♦ Do not use this meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitter, or other electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

♦ Use this instrument in a dry environment, if synthetic materials are present (synthetic clothing, carpets etc.) it may cause damaging static discharges that may cause erroneous results.

WARNINGS AND CAUTIONS REGARDING THE TEST STRIPS

♦ Do not use test strips more than once.

♦ It should not be used for testing newborns.

♦ It should be used only for testing capillary and vein.

♦ It should not be used for serum or plasma.

♦ A red blood cell count (hematocrit) that is higher than 70% or lower than 10% can cause false test results.

C. GENERAL INFORMATION

The DA12 meter measures the small electrical current and displays the blood glucose results. The current is produced from the blood glucose mixing well with chemicals on the test strip. User needs to apply 0.6μL of fresh capillary or vein for one test, and the test result will be displayed in 6 seconds. The strip ejection function of DA12 meter can help users avoid the risk of contamination after testing. Besides that, DA12 meter also has unique strip technology with auto coding system. Users do not need to code the glucose meter.

D. KNOW THIS UNIT

PACKAGE CONTENT

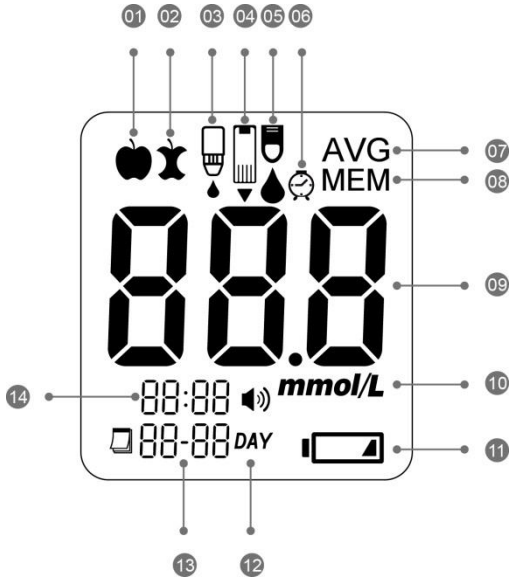
♦ DA12 Meter X 1	♦ Carrying Case X 1
♦ Lancing Device X 1	♦ User Guide X 1
♦ Alkaline AAA Battery X 2	♦ Logbook X 1
♦ Lancets (10 pcs) X 1	♦ Glucose Strip (10pcs) X 1
♦ Control Solution X 1	

PRODUCT AND METER DISPLAY

♦ Main Unit

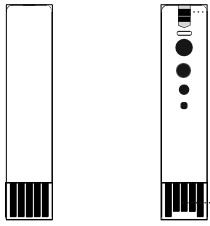
L

♦ Function Display



- ♦ 1.Glucose PC test mode
- ♦ 2.Glucose AC test mode
- ♦ 3.Control solution test mode
- ♦ 4.Test strip symbol
- ♦ 5.Blood drop symbol
- ♦ 6.Alarm symbol
- ♦ 7.Average symbol
- ♦ 8.Memory symbol
- ♦ 9.Test results
- ♦ 10.Test unit
- ♦ 11.Low battery reminder
- ♦ 12.Day of average
- ♦ 13.Date
- ♦ 14.Time

DA12 TEST STRIP



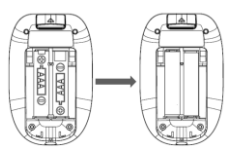
⚠ Warning: Touch the drop of blood to the top edge of the test strip. Don't smear sample on the strip.

E. HOW TO USE

BATTERY INSTALLATION (Replace New Batteries)

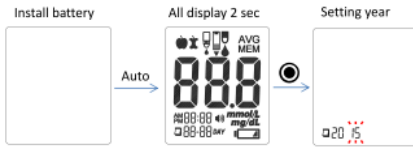
1. Turn off meter and turn DA12 to the back side and open the battery compartment.

2. Insert two Alkaline AAA batteries correctly.



3. Push back the battery compartment until hearing a “click” sound.

4. Try to turn on the device then see whether the DA12 can be powered on, the screen will show all symbols for 2 second at this time. If not, please check the above steps.



5. After displaying all icons, it will enter into year setting mode. If completing replacement of the batteries within 3~5 seconds, the original setting of meter can remain unchanged, and will not require re-set.

General Advise on The Handling of Batteries

♦ Replace the worn batteries with new ones immediately.

♦ Take the batteries out of meter if the meter will be not used for long time.

♦ If user leave the unit without using it for a long time when the batteries are included inside, leakage from the battery may occur leading to trouble.

♦ Do not use new and worn batteries together or different types of batteries together.

♦ Insert the batteries with the polarities (+ and –) in correct alignment.

♦ When handling the batteries, be sure to read the notes on the batteries.

♦ Dispose of old batteries according to local environmental regulations.

Battery Life and Replacement

1. When the symbol shows on the screen, it means the battery power is low and need to replace batteries as soon as possible. In case the meter is in this situation, even the battery power is low, user still can use DA12, but we strongly suggest user replace the batteries as soon as possible.
2. There is no enough power to support DA12 to operate when the symbol is showing on screen after powering on. Thus, the meter will be shut down after 120 seconds when the symbol is showing on screen after powering on. It represents that the battery power is too low to perform a test. User has to replace the batteries to continue using the DA12 meter. Time and date must be reset after replacing the batteries, but the records still remain.

METER SET UP (Year/Date/Time)

1. Press and hold middle button

   When user replace new batteries, the screen will be showing all symbols for 2 second, and enter the year setting mode.

2. Setting the year Voice Assistant Please select the year

   Once the meter enters the year setting mode, the last two digits of the year will flash.

   (1) Click the right button to increase the year.

   (2) Click the left button to decrease the year.

   (3) Click the middle button to save setting. Then the display will enter the month setting mode.

3. Setting the month Voice Assistant Please select the month

Once the meter enters the month setting mode, the month field will flash.

(1) Click the right button to increase the month.

(2) Click the left button to decrease the month.

(3) Click the middle button to save setting. Then the display will enter the day setting mode.

4. Setting the day Voice Assistant Please select the day

Once you enter the “Day” setting mode, the day field will flash.

(1) Press the right button once to increase by a day.

(2) Press the left button once to decrease by a day.

(3) Press the middle button to save the “Day” setting and enter the “Hour” setting mode.

5. Setting the hour Voice Assistant Please select the hour

Once the meter enters the hour setting mode, the hour field will flash.

(1) Click the right button to increase the hour.

(2) Click the left button to decrease the hour.

(3) Click the middle button to save setting. Then the display will enter the minute setting mode.

6. Setting the minute Voice Assistant Please select the minutes

Once the meter enters the minute setting mode, the minute field will flash.

(1) Click the right button to increase the minute.

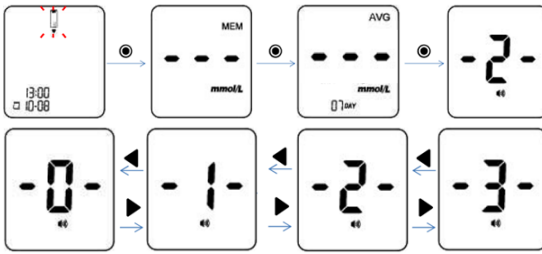
(2) Click the left button to decrease the minute.

(3) Click the middle button to save setting. The time settings are completed.

METER SET UP (Speaking Volume)

There are four speaking volume options (0/1/2/3) to choose from. Power on meter and then screen will show strip symbol. Press middle button 3 times then switch to voice volume setting mode.

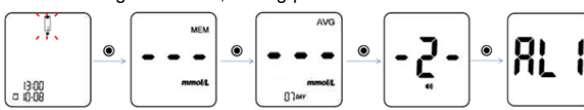
Press right button can increase speaking volume, press left button can decrease speaking volume. Volume 0 indicates that the speaking function is turned off. After choosing suitable volume, press middle button to confirm volume setting.

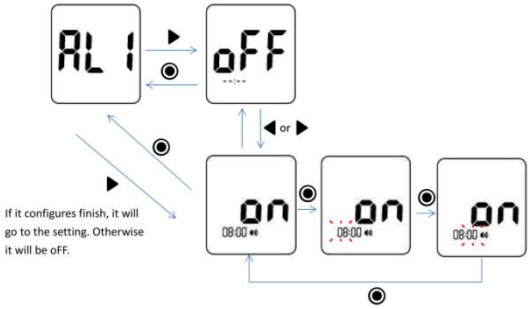


METER SET UP (Test Reminder Alarm Setting)

You may set up any or all of the reminder alarms (AL1-4). The meter displays “On” or “Off”; press Middle button to turn on or turn off to set the first reminder alarm.

Press Middle button 4 times and switch to alarm setting mode. Press Right button to select “On” or “Off” and press Middle button to confirm. If choose “On”, press Left/Right button to set hour and press Middle button go to minutes, then press Left/Right button to set minutes. Press Middle button to confirm, then screen will back to AL1. Press Middle button go to AL2~4, setting procedure is the same.





At the pre-set alarm time, the meter will beep and screen will show “on” and automatically turn off after 3 minutes. You can press Middle button to turn off alarm and then insert test strip to begin testing.

PREPARATION BEFORE BLOOD GLUCOSE TESTING

Please prepare the materials you need for testing as listed below. Read this user guide and test strip manual carefully to ensure the correct testing process and results.

- DA12 Blood Glucose Meter
- DA12 Blood Glucose Test Strip
- Antiseptic Wipes or Alcohol Wipes
- Lancing Device
- Lancet

Note:

This product provides four modes for measuring as the following table, for more details of the process.

	Mode	Symbol	Meaning
1	Regular test mode	N/A	Any time of a day without regard to time since last meal

2	Glucose AC test mode		Without food intake at least eight hours
3	Glucose PC test mode		Two hours after meal
4	Control solution test mode		Testing with control solution

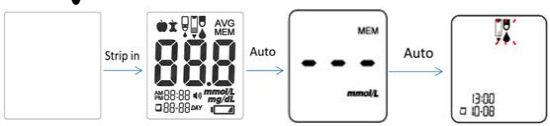
- Preparation of test strip

1. Insert the Test Strip into the strip slot correctly and the DA12 meter will turn on. All LCD segments will display for 2 second.

Insert the test strip (Correctly)

* Do not insert the strip from reverse side.

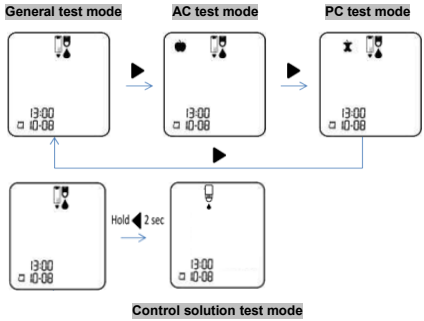
2. While meter is power off, the screen will shows all display for two seconds then shows the latest test result and then drop symbol will appear.



Your Meter is ON

Please apply blood to the test strip

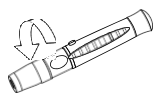
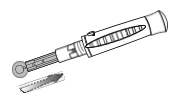
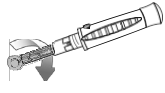
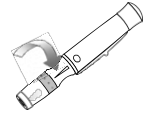
3. While drop symbol will appear, you can press right button, to switch between General test mode – AC test mode – PC test mode. Press and hold left button 2 seconds to switch Control solution test mode.



- Preparation of Lancet

1. Install a new lancet to the lancet holder correctly and make sure it is seated firmly. Then remove the protective cap.

2. Adjust the puncture depth by the selection dial (Normally at the 2nd level), twist to a suitable number. (Smaller numbers are for shallower punctures and larger numbers are for deeper puncture)

	
a. Open up the case of lancet device.	b. Install the lancet.
	
c. Twist the protective cap on the lancet.	d. Adjust the puncture depth.

3. Slide the barrel control back until it clicks. The lancing device is ready to use.

- Wash Hands and Puncture Site

Wash hands with soap and warm water. Rinse and dry thoroughly.

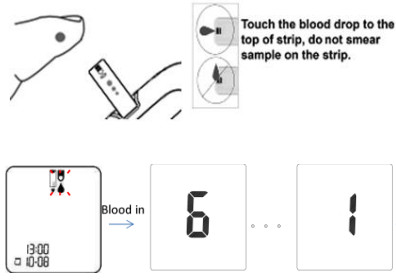
BLOOD GLUCOSE TESTING

1. Please massage fingertip gently, it will help user to obtain smooth blood flow.
2. Please choose a different puncture site each time.

- ⚠ Warning: Keep lancing device and single use lancet away from children; it could be hurtful for them.
- ⚠ Warning: Please make sure hand is dry before taking the blood sample.
- ⚠ Warning: Use a single use lancing device or lancet.
- ⚠ Warning: Read this system user guide before use.
- ⚠ Warning: We suggest that user should use a different puncture area each time. Repeated punctures in the same place may cause pain.
- ⚠ Warning: The DA12 glucose strip only needs about 0.6 μL of fresh whole blood, do not squeeze too much blood from the puncture site.
- ⚠ Warning: Always use a new lancet to avoid contamination before testing.
- ⚠ Warning: Lancet is single use only, cannot reuse.

3. Blood glucose test

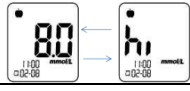
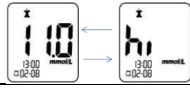
Touch the blood drop to the tip of the confirmation window of test strip. The test result will appear on the screen after 6 seconds.

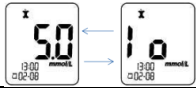
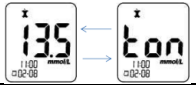


Your blood glucose reading is 13.5 millimol per liter

4. Blood Glucose Result Indicators

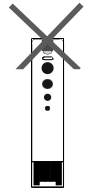
If your blood glucose test results over a setting value, different warning indicators will show on the screen. Indicators' meaning is as below:

Warning indicators	Meaning
	Your Before Meal blood glucose test result is higher than 7.8 mmol/L.
	Your Before Meal blood glucose test result is lower than 3.8 mmol/L.
	Your After Meal blood glucose test result is higher than 10.0 mmol/L.

	Your After Meal blood glucose test result is lower than 5.5 mmol/L.
	Your GENERNAL blood glucose test result is higher than 8.9 mmol/L.
	Your GENERNAL blood glucose test result is lower than 3.8 mmol/L.
	Your blood glucose test result is higher than 13.3 mmol/L. You might be at a risk of developing diabetic ketoacidosis.
	

Remark: The warning indicators are just for reference only, and when you see the warning indicators after testing, please consult with your doctors.

Sample filled yellow zone fully



Sample too small

Precaution:

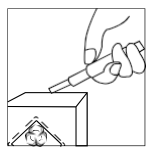
- ♦ Check the yellow zone is filled with sample.
- ♦ Do not apply sample to the strip more than once.
- ♦ The blood sample must be 0.6 μL.
- ♦ Test immediately when fresh sample is ready.
- ♦ Wash hands with soap and water after test.
- • ⚠ Warning: If the results do not match what user feel, please test again with a new strip.

5. Strip ejection

Press the strip ejection button to remove the strip to avoid blood contamination.

Notice: The meter will turn off automatically after removal of the test strip.

6. Dispose of used strip and lancet properly



The following items will cause inaccurate results:

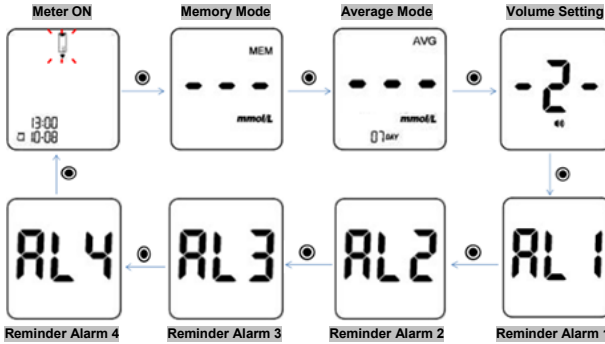
- The confirmation window does not fill completely.
- Applying sample more than once.
- Testing for newborns.
- Not use for testing fresh whole blood.
- Applying sample to test strip after a long period of time when the drop symbol flashes.
- Sudden or huge variation of environment during measurement.
- Using a false test strip.
- Test sample HCT (hematocrit) that the red blood cell count is higher than 70% or lower than 10%.

⚠ Warning: Please follow proper precautions in accordance with local regulation when disposing of all materials.

F. ABOUT MODES

MODE CHANGING

Press the middle button ◉ can change modes as the followings operation flow. More details, please refer to the below relative mode description.



Memory Mode

- To Check The Test Results

1. Press the middle button to turn on the DA12, follow mode changing operation flow to choose the memory mode. In memory mode, **MEM** symbol will appear and the screen will show the latest test result first. Number “512” below test result means the latest result.

2. User can press left button to review previous test results.

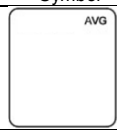
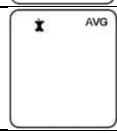
3. DA12 meter is able to store up to 512 test results together with date and time, including all test results of regular, AC, PC, and control solution.

Average Mode

- To Average the Test Results

Note:

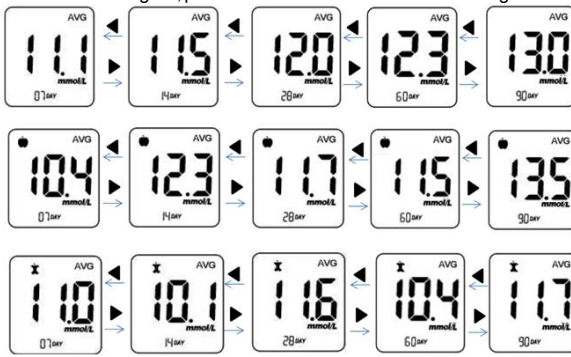
This product provides three modes for records averaging as the following table; the result in control solution mode will not be included in any average mode.

Mode	Symbol	Meaning
General Average mode		Any time of a day without regard to time since last meal
Glucose AC average mode		Without food intake at least eight hours
Glucose PC average mode		Two hours after meal

- To Average The Test Results

1. Press the middle button to turn on the DA12, follow mode changing operation flow to choose the average mode. The **AVG** symbol will appear and the screen will show average of last seven days first.

2. Follow below figure, press middle button to choose the average mode.



G. DATA TRANSMISSION

The advantage of downloading test results to a PC

Due to the limitation of data storage of the DA12 meter, we recommend user download test results to a PC regularly and it will be helpful for user to monitor the long term trend of blood glucose.

Glucose management software enables you to download your test results to PC to further manage and monitor glucose levels.

- How to Download Test Results to a PC

- In order to download test results to a PC, you need

(1) USB cable made by DELBio

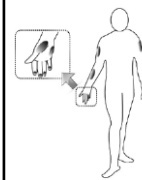
(2) Glucose management software (Download from DELBio website)

- Connecting DA12 to a PC by the USB cable.
- Please refer to DELBio website for information about how to operateand manage your glucose information Glucose management software.

H. ALTERNATE SITE TESTING

General Information of Alternate Site Testing

Users have the options of testing other sites on body besides the fingertip. Users can test the palm, forearm and upper arm as well. While fingertip blood can be tested at any time during the day, there are times when testing from any other approved site is not ideal— usually when blood glucose is rapidly changing. Please read the following section before testing from other areas.



Caution:

1. Talk to healthcare professional about AST (Alternate Site Testing).
2. Do not change treatment because of just one result.
3. **NEVER** ignore symptoms of high or low blood glucose.
4. If blood glucose does not match how users are feeling, perform a fingertip test to confirm result. If the fingertip result still does not match how user feel, please refer to the following several items and contact with healthcare professionals.

Alternate site testing may be done:

- Immediately before a meal
- Fasting

DO NOT test from an alternate site:

- Two hours or less after eating
- After exercising
- If user is sick
- If user think blood glucose is low
- If user often don't notice when blood glucose is low
- When basal insulin is most active
- After injecting rapid-acting insulin (two hours or less)

- How to AST

User need the meter, a test strip, a lancing device designed for AST, and the clear AST cap.

1. Unscrew the adjustable tip, insert a new lancet firmly into the carrier. Twist off lancet protective cap and replace the AST Cap. Sliding barrel signals readiness with a soft click.

2. Insert a test strip into the meter in the correct direction. The meter turns on.

3. A flashing blood drop symbol appears on the screen.

4. Gently massage the alternative site that user would like to draw blood from.

5. Clean hands and the alternative site user will puncture. Press the lancing device firmly against a fleshy area on the alternative site. Press the lancing device up and down in a slow pumping motion to assist the flow of blood.

6. Trigger the lancing device will be keeping steady pressure on the puncture site. Immediately lift the lancing device off of the site.

7. Squeeze the puncture site with appropriate pressure slowly to get enough blood.

8. Slightly touch the top of strip with the blood to make enough blood filled in strip; user can get the test result after 6 seconds.

⚠ Warning: The AST function of DA12 meter can be used for the following sites: palm and forearm.

⚠ Warning: Please follow the lancing device manual to execute AST blood sampling from puncture sites.

I. GLUCOSE CONTROL SOLUTION TESTING

ABOUT CONTROL TESTING

In order to provide you an accurate test result, we suggest running a control test to check if the meter and test strips are working properly. When the control result is inside the range on the test strip container, the test strips and meter are working properly.

Important:

- Use Only the DAE01 glucose control solution with the DA12 meter and DA12 strips.
- Mark the first opened date of control solution; discard any unused control solution over three months after opening .
- Store the bottle at 4 ~ 30 degree Celsius (39 ~ 86 degrees Fahrenheit) and relative humidity 10% ~ 90%RH. Do not refrigerate it.
- Shake the control solution bottle before use. Please use a new control solution if control solution deteriorates or coagulates.

Before running the test, please place the DA12- B2 meter, test strips and glucose control solution at room temperature for 30 minutes to reach the balance of temperature before use.

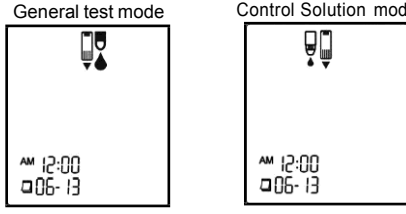
♦ When to run the glucose control solution test?

- The test strip vial is opened for long time or you think the test strips have been damaged.
- When the meter could be damaged or not working properly.
- When user want to double check on the meter's performance.

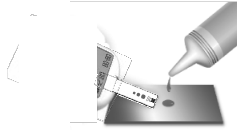
HOW TO CONTROL TEST

Running a Control Testing:

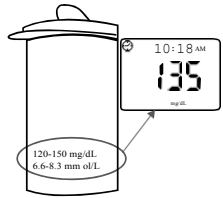
1. Prepare the meter and test strip.
2. Insert the test strip into the meter correctly.
3. Then the screen shows the symbol.
4. Press the left button 2 seconds to enter control solution test mode, and the control solution symbol appears.



5. Mix the control solution well before test.
6. Squeeze a tiny drop on a clean surface.
7. Touch the tip of the test strip to the drop of control solution.



8. And the result will show on screen after the meter countdown from 6 to 1.
9. Compare the result with the control range printed on the strip vial.
10. When the control result falls inside the control range, the test strips and meter are working properly.



* Write the date user first open the bottle on the bottle label. The control solution must be discarded after three months from the date the bottle was opened, on the “discard date or on the “expired date on the bottle label, whichever comes first. Do NOT use control solution that is past the “expired or discard date.

⚠ Warning: Before running test glucose control solution test, always check the expiration date. Do NOT use control solution if expired over six months of the first opened day.

J. CARE AND MAINTENANCE

CARING FOR STRIPS

Wash hands before testing.

♦ Check the expire date printed on the package and do not use expired strips.

♦ Mark the opened date on the test strip bottle label when user opens it at the first time.

♦ Discard the bottle and remaining test strips after 6 months from the opened date.

♦ Keep the strip bottle away from direct sunlight and heat, and store at 1 ~ 30 degree Celsius (33.8 ~ 86 degrees Fahrenheit) and relative humidity below 90%RH.

♦ Do not refrigerate the test strip.

♦ Do not transfer the test strips into other containers.

♦ Always close the container tightly immediately after taking a test strip out.

♦ Keep the test strip from getting dirty during storage.

CARING FOR METER

♦ If the meter's surface gets dirty, gently wipe with a cloth slightly dampened or use a mild detergent.

♦ For medical staff, user may use a 10% bleach, 70% alcohol (ethanol), or 10% ammonia scouring reagent.

♦ Do not clean the test strip slot.

♦ Do not put any liquid into the test strip slot or on the buttons of the meter.

♦ Do not put the meter under water or any liquid.

♦ The meter must be stored at room temperature.

⚠ Warning:

- If the control result does not fall inside the range printed on test strip container, do not use this meter until the problem is resolved.
- Please contact physicians if the second control solution test result still failed.

⚠ Warning:

- If the result always fails to be inside the expected range, please check the following points:

  Did user follow the testing instructions correctly?

  Are the test strips or control solution expired?

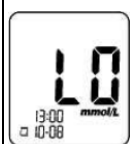
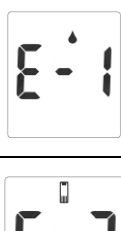
  Is there a DA12 meter defect in materials or workmanship?

If user still has any problem, please contact local authorized distributors for more information.

K. TROUBLESHOOTING

When the meter is used incorrectly, in poor condition, or other unexpected events happen, the screen will show an error message to alert user to notice the problem arising and user should resolve the issue according to the following troubleshooting table.

The following messages may mean user has obtained a result that requires immediate attention or there may be a problem with the meter.

Message	Symbol	Meaning	Action
HI		User may have a very high blood glucose level. (> 600 mg/dl, 33.33 mmol/L,)	1.Do control solution test. 2.Redo blood glucose test. 3.Contact healthcare professionals.
LO		User may have a very low blood glucose level. (< 20 mg/dl, 1.11 mmol/L)	1.Do control solution test. 2.Redo blood glucose test. 3.Contact healthcare professionals.
Apply blood too early		Blood sample applied too soon to strip	Follow instruction step.
Wrong Strip		Test strip could be expired, upside down, broken, or used.	1.make sure if strip inserting correctly. 2.use a new DA12 strip to test.

Message	Symbo	Meaning	Action
Temperature out of range		You may have tested near the low or high end of the meter's operating temperature range. (10~40 degree Celsius /50~104 degrees Fahrenheit)	Repeat the test after the meter has reached a temperature within the operating range.
Low Battery		The power is too low to perform a test.	Replace the batteries.
Lack of blood volume		Applied blood sample was too small.	Replace another new strip, and apply enough blood sample.(>0.6μl)
Strip Damage		The strip could be broken and cannot be used	Please test with a new strip

L. LIMITED WARRANTY

It's guaranteed that the original purchaser of the meter that this product will be free from defects in materials and workmanship for two years from the date of purchase. If, during this two years period, the meter does not work properly because of a defect in materials or workmanship, please contact with the dealer. The warranty applies only to the original purchaser of the meter.

It's warranted that when following the instructions or leaflet, DA12 series meters can work properly.

Instruments subjected to misuse, abuse, neglect, unauthorized repair or modification will be excluded from this warranty. If user is not fully satisfied with DA12 meter, please contact local authorized distributors for more information.

⚠ Warning: When no longer needed, remove the batteries and dispose of the meter according to local regulations.

M. SPECIFICATION

Product	Blood Glucose Monitoring System
Model	DA12
Power Supply	Alkaline AAA batteries x 2
Battery Life	1000 times
Measuring Range	20~600mg/dl (1.11 mmol/L ~ 33.33 mmol/L)
Calibration	Plasma- equivalent
Measuring Unit	mmol/L
Measuring Time	6 seconds
Sample Type	Capillary and vein drawn from the fingertips, palm, forearm
Blood Sample Size	0.6 µL
Operating Temperature	10~40 degree Celsius /50~104 degrees Fahrenheit
Meter Storage Temperature	-20 ~ 60 degree Celsius/ -4 ~ 140 degrees Fahrenheit
Relative Operating Humidity	10% ~ 85%RH
Memory Capacity	512 results with date, time and unit for the last 7, 14 and 28 days
Dimension	91 mm x 58.1 mm x 28.9 mm (L×W×H)
Weight	95 g with batteries
Transmission	User can upload data to PC via transmission function

	MANUFACTURER		CONSULT INSTRUCTIONS FOR USE
	CAUTION	LOT	BATCH CODE
	TEMPERATURE LIMITATION	EC REP	AUTHORISED REPRESENTIVE IN THE EUROPEAN COMMUNITY
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE	CE	
	DO NOT REUSE		KEEP AWAY FROM SUNLIGHT
SN	SERIAL NUMBER	STERILE R	STERILIZED USING IRRADIATION
	USE BY		KEEP DRY
REF	CATALOGUE NUMBER		DO NOT USE IF PACKAGE IS DAMAGED

For self-testing

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IVD

CE 0120

For UK Use Only

Please read this information before using DA12 meter.
This instruction is helpful to understand the operation.