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Preface

Thank you for choosing the RIGHTEST ALPHA Blood Glucose Monitoring System. Please read this manual thoroughly before testing. It provides all information you need to use the product. The RIGHTEST ALPHA Blood Glucose Meter must only be used with RIGHTEST ALPHA Blood Glucose Test Strip and RIGHTEST Control Solution. The application of other Test Strips or control solutions can lead to incorrect results.

We hereafter call RIGHTEST ALPHA Blood Glucose Meter as RIGHTEST ALPHA Meter, and RIGHTEST ALPHA Blood Glucose Test Strip as RIGHTEST ALPHA Test Strip for short.

It is recommended to monitor blood glucose regularly. RIGHTEST ALPHA Blood Glucose Monitoring System is accurate and easy-to-use and is thus your reliable assitant for diabetes management.

RIGHTEST ALPHA Blood Glucose Monitoring System is manufactured and supported by Bionime Corporation. If you have any question or concern, please contact your local Bionime Customer Service or email to info@bionime.com.

The RIGHTEST ALPHA Blood Glucose Monitoring System is designed for *in vitro* diagnostic (for testing outside the body) use only and can be used by home user and healthcare professional.

The system can test glucose concentration in fresh capillary whole blood (drawn from fingertip, palm and forearm). The glucose result displayed is calibrated into the plasma glucose testing equivalent.

The system is not intended for screening or diagnoses of diabetes mellitus.

Intended Use

Caution

- Before using RIGHTEST ALPHA Blood Glucose Monitoring System to test your blood glucose, please read all of the info and conduct all of the tests including the quality control test.
- We recommended you to perform the quality control test regularly to ensure the test results are accurate.
- The RIGHTEST ALPHA Meter can only be used with RIGHTEST ALPHA Test Strip. Other brands' test strips should not be used under any circumstances. The use of other brands' strips may give inaccurate results.
- If RIGHTEST Meter and Test Strips are exposed to temperature environments out of range for the meter – below 10°C (50°F) or above 40°C (104°F) – please wait at least 30 minutes before testing again.
- Follow all environmental protection regulations when disposing of batteries, strips and lancets.
- RIGHTEST Blood Glucose Monitoring System has not been validated for use on neonates. DO NOT use it test for neonates.
- RIGHTEST Blood Glucose Monitoring System is NOT intended for arterial blood testing.
- Avoid contact with dripping or splashing liquids.
- Once patient is suspected as rare disease (e.g. galactosemia), the glucose result should basedon laboratory test.

- The minimum blood sample size for testing is 0.75 μ L :(•)

Sample Size Example	0.75 µL	1.0 µL	1.5 µL	2.0 µL	3.0 µL	
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Blood sample size above $3.0 \ \mu$ L might contaminate the test strip port and the meter. Blood sample size below $0.75 \ \mu$ L may cause an inaccurate result or may prevent a meter reading. An Er4 reading will be displayed if the sample size is too small. In this case, repeat the test with a new test strip.

// Important Safety Notes

- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after following the cleaning and disinfecting procedures. Please refer to the section "Maintain the products" on page 35.
- Users should wash their hands thoroughly with soap and water before and after handling the meter, lancing device, or test strips.

Caution

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RIGHTEST ALPHA Blood Glucose Monitoring System

Your RIGHTEST ALPHA Blood Glucose Monitoring System consists of several items. Please identify each item and make sure you understand how to use them.

The following items are included in your RIGHTEST ALPHA Blood Glucose Monitoring System:

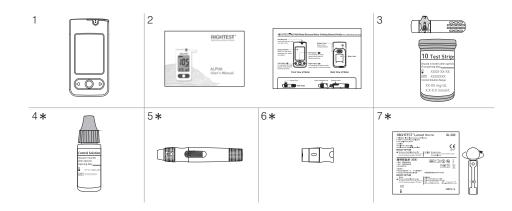
1. RIGHTEST ALPHA Blood Glucose Meter (with 1 CR2032 battery installed)

2. Instruction documents (Getting Started and User's Manual (includes Log Book, Warranty Card, Emergency Card))

- 3. RIGHTEST ALPHA Blood Glucose Test strips (10/25 pcs)(with Insert) *
- 4. RIGHTEST Control Solution GC570 (with Insert) *
- 5. RIGHTEST Lancing Device GD500 (with Insert) *
- 6. Clear Cap *
- 7. Disposable Sterile Lancets (10 pcs) *
- 8. Carrying Case (not shown) *

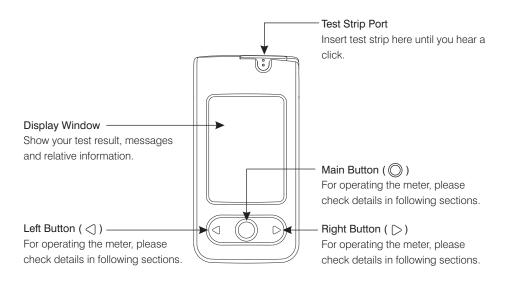
(*Different packages have different bundled items. Some of packages might not include * items.)

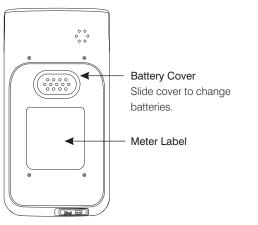
RIGHTEST ALPHA Blood Glucose Monitoring System

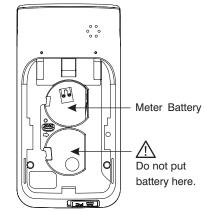


RIGHTEST ALPHA Meter

RIGHTEST ALPHA Meter





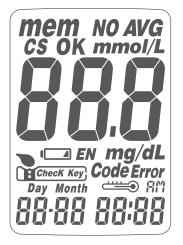


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RIGHTEST ALPHA Meter

RIGHTEST ALPHA Meter

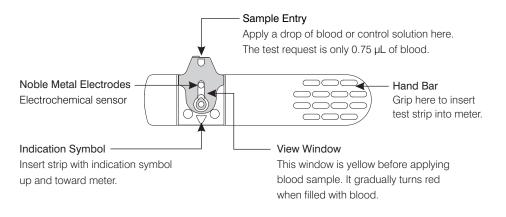


mem	Indicates a test result stored in memory		Tell when to apply the blood sample
NO AVG	Indicates a test result, not joining into the Average function of this meter		Test strip
AVG	Indicates with the average result	Error	Indicate error happens
CS	Indicates a control solution test result	Day Month	Current date under time mode or Testing date under memory mode
mmol/L mg/dL	Unit of test result		Indicates if the environmental temperature is exceeded during testing
888	Test result	8M	Indicates the time in 12H format
1	Warns when the battery is low or must be replaced	88:88	Current time under time mode or Testing time under memory mode
OK EN Check Key Code Manufacturing use only			

RIGHTEST ALPHA Test Strip

The RIGHTEST ALPHA Meter must only be used with RIGHTEST ALPHA Test Strip and RIGHTEST Control Solution.

The application of other Test Strips or control solutions can lead to incorrect results.





Electrode Contacts Sensing signal output terminals.

RIGHTEST ALPHA Test Strip

PRECAUTION

- Close the test strip vial immediately after taking out a test strip.

- Do not reuse test strips. Test strip can be only used once.
- Do not use expired test strips.
- Every time when you open a new vial of test strips, please write the opening date on the label. Use test strips within 3 months after opened or until the expiration date printed on the label (whichever comes first).
- Store the test strips in 4 30°C (39 86°F) and with 10 90% relative humidity. Do not expose to direct sunlight or heat.
- For detailed information, please refer to the RIGHTEST ALPHA Test Strip Insert.
- If the RIGHTEST ALPHA Meter or strips are exposed to a substantial change in temperature. please wait at least 30 minutes before testing again.

Meter activation and Battery change

Your meter comes with 1 CR2032, 3 volt, batteries installed. A new batteries will provide power to perform about 1,000 tests under normal use. You can press the main button or insert a strip to activate your meter.

1. Turn the meter over.



2. Install the battery. Be sure to put battery in correct way with the "+" symbol up.



Meter activation and Battery Change

- 3. Slide the battery cover back until it snaps into place.
- 4. The meter performs a self test.

Press and push battery

cover to open.

- 5. Press any button to exit the self-test and enter Setting Mode.
- 6. Set the time and date when the batteries are replaced. See Chapter "Setting up your meter setting the time, volume and date". Test results are still stored in the memory.



PRECAUTION

- Please follow the local regulations and discard a used battery properly.

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Setting Up Your Meter- Setting the Time Date, Volume and Test Unit

You can enter Setting Mode by below two ways.

1. Reload battery

After removing the battery, please press the main button for several times until no signal on screen, then follow the battery installation steps to load batteries. The meter will do self test. Press the main button to exit the self test and enter Setting Mode.

2. With Battery inserted

Press the main button first to turn on the meter. Then press and hold the main button for 7 seconds (the meter will first show backlight, then be turned off during this period, please keep pressing) until you hear a beep, indicating you have successfully entered Setting Mode. The display screen will show setting data.

// NOTE

- When you keep pressing the main button for 3 seconds, the display on screen will turn off. Please don't care it. Keep pressing the main button till entering setting data.
- Quick press the main button allows you to change setting. However, if you want to return to the time mode, you need to go through all the settings first by pressing quickly the main button.

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Setting Up Your Meter- Setting the Time Date, Volume and Test Unit

1. Year setting

With the year format blinking, press the Left or Right button to adjust it. Then press the Main button to confirm it. Then it will move to Month setting.



2. Month setting

With the month blinking, press the Left or Right button until the current month appears. Then press the Main button to confirm it and move to Day setting.



Day setting

With the day blinking, press the Left or Right button until the current day appears. Then press the Main button to confirm it and move to Time format setting.



Setting Up Your Meter- Setting the Time Date, Volume and Test Unit

4. Time format 12/24H selection

With the time format blinking, press the Left or Right button to adjust it. Then press the Main button to confirm it and move to hour setting.

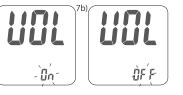
5. Hour setting

With the hour blinking, press the Left or Right button until the current hour appears. Then press the Main button to confirm it and move to minute setting.

6. Minute setting

With the minute blinking, press the Left or Right button to adjust it. Then press the Main button to confirm it. Meantime, it will shift to next digit for setting. Then it will move to volume setting.

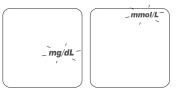
7. Volume setting

With the volume blinking, press the Left or Right button to turn it on or off. Then press the Main button to confirm and finish the setting. 

Setting Up Your Meter- Setting the Time Date, Volume and Test Unit

8. Setting of Test Unit

With milligrams per deciliter (mg/dL) or millimole per liter (mmol/L) blinking, press the Left or Right button to switch. Then press the main button to confirm it and finish the settings (*According to different regulations in different countries/regions, the unit of the meter may be fixed at mg/dL or mmol/L and cannot be changed. In this case, please skip this step and go directly to the next step).



9. Ending setting

After test unit setting, for confirmation you will hear a beep (if volume is turned on). All the settings are saved and completed and will return to time screen. (If Volume is turned off, the display will directly return to time screen without a sound of "beep".)



/ NOTE

- When the meter is idle for more than 2 minutes, the meter will leave setting mode and power off automatically.

Turning On / Off the Meter

1. How to turn on the Meter

Press the Main button or Insert a test strip.

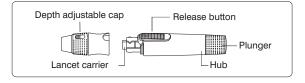
2. Manual Power off

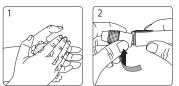
If you want to turn off the meter, please keep pressing the Main button for 4 seconds.

3. Auto Power off

The meter will power off automatically if you don't operate it over 2 minutes.

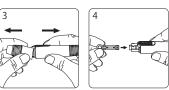
Performing a Blood Test





1. Wash your hand with warm soapy water and dry thoroughly.

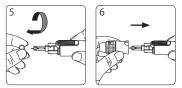
2. Hold the depth adjustable cap in one hand and hold the hub in the other hand. Bend the cap towards the down side, until a gap appears between the cap and hub.



3. Pull the cap and hub off in opposite directions, remove the

cap.

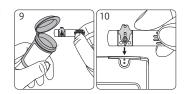
- 4. Insert a new disposable lancet firmly into lancet carrier.
- 5. Twist off and set aside the protective cover of the disposable lancet.



6. Replace the depth adjustable cap.

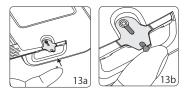
Performing a Blood Test

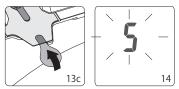
- 7. Choose a depth of penetration by rotating the top portion of the depth adjustable cap until the setting depth matches the window. Settings are based on skin type "umo" for soft or thin skin; "umo" for average skin; "umo" for thick or calloused skin.
- Hold the hub in one hand and pull on the plunger in the other hand. The device will be cocked. Release the plunger, it will automatically move back to its original position near the hub.
- 9. Take one strip from the vial. Close the vial cap immediately.
- Insert the strip into the strip port of the meter with the view window facing up. The meter confirms the insertion of the strip with a beep (if volume is turned on).



- 11. A blood drop symbol appears and is accompanied by a further beep (if volume is turned on). Now you can apply the blood sample within 2 minutes.
- 12. Place the lancing device against your fingertip and press the release button.
- 13. Touch and hold the drop to the edge of sample entry until you hear a "beep" (if volume is turned on) and the View Window is filled with blood. If the View Window is not completely filled with blood, the test will not start, please discard the test strip and repeat the test with a new test strip.
- 14. You will see the countdown mode on the screen. After 5 seconds, the test result appears.

Performing a Blood Test





Performing a Blood Test

- 15. Pull off the depth adjustable cap. Without touching the used disposable lancet, stick the lancet tip into the protective cover.
- 16. Holding the release button in one hand I (see picture 16, step 1) and pulling on the plunger in the other hand (see picture 16, step 2) will safely eject the used disposable lancet.
- 17. Discard the used disposable lancet into an appropriate punctureproof or biohazard container.
- 18. Replace the depth adjustable cap after finishing the test.

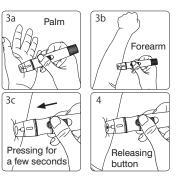
- Do not apply your blood drop to the sample entry on the strip until you see the " " " appear. The meter is performing an internal test and will display " " and " *Error* " if you apply blood too soon. Please repeat the test with a new test strip.
- Every time when you open a new vial of test strips, please write the opening date on the label. Use test strips within 3 months after opened or until the expiration date printed on the label (whichever comes first).

 Always keep the metal contact points of the test strip entry point clean.
 If any dust or impurities are present, please clean with a small soft brush, otherwise the meter may not work correctly when you insert a test strip.

the label. Use					
	10 Test Strips				

Alternative site testing-palm or forearm blood sampling

- 1. Choose Clear Cap and follow step 1 5 on page 23.
- 2. Massage the puncture area of palm or forearm for a few seconds.
- Immediately after massaging the puncture area, press and hold the lancing device with the Clear Cap against palm or forearm.
- 4. Then press the release button.
- Continue holding the lancing device against palm or forearm and gradually increase pressure for a few seconds until the blood sample size is sufficient.
- 6. Follow step 9 18 on page 24 26 to complete the test and discard the used disposable lancet.



Alternative Site Testing (AST)

Alternative Site Testing (AST)

♠ PRECAUTION

- $^{
 m A}$ Consult your healthcare professional before sampling from your palm or forearm.
- Test results using samples from the palm or forearm may vary at times when glucose is changing rapidly (e.g. drinking, eating, using medication, exercise). In such circumstances, only fingertip blood samples should be used.
- Fingertip samples may show rapid changes in glucose faster than palm or forearm samples.
- Since blood flow from the palm or forearm may be slower than from the fingertip, use the clear cap on the lancing device to observe the size of the acquired blood droplet.
- DO NOT test from the palm or forearm if testing for insulin dosage calculation or hypoglycemia (low blood glucose).
- Palm or forearm results should not be used to calibrate continuous glucose monitors (CGMs).

Make sure your blood sample covers the whole area of the View Window to get an accurate test result. An insufficient blood sample will result in an error message ("Er4"). If this occurs, repeat the test with a

new test strip.

Insufficient blood sample

mple Enough blood sample

View Window appearance

- Check the expiration date printed on the strip vial every time you use a test strip. Do not use expired test strips.
- Use each test strip immediately after taking out from the vial.
- Do not reuse test strips.
- If RIGHTEST Meter or Test Strips is exposed to temperature environments out of range for the meter – below 10°C (50°F) or above 40°C (104°F) – please wait at least 30 minutes before testing again.
- Apply the blood drop only on the sample entry of the test strip.
- Please don't drip or inject the blood sample directly by syringe to the sample entry of test strip. Doing this might contaminate the meter or cause damages and is not recommended.



"Lo" and "Hi" readings

The RIGHTEST ALPHA Meter displays results between 10 - 600 mg/dL (0.6 and 33.3 mmol/L). If your test result is below 10 mg/dL (0.6 mmol/L), "*L a*" will appear on the screen. Please repeat your test with by a new test strip. If you still get "*L a*" result, you should immediately contact your healthcare professional. If your test result is above the high end of the system's detection range 600 mg/dL (33.3 mmol/L), " *H*^{*n*}" will appear on the screen. Please repeat your test with a new test strip. If you still get " *H*^{*n*}" result, you should immediately contact your healthcare professional.

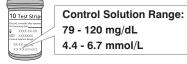
L Q Mg/dL 20211 H Mg/dL 20211

NOTE

- If your blood glucose result is unusually high or low, or if you question your testing results, repeat the test with a new test strip. You can also run a Quality Control Test to check your meter and test strip. If the test result still remains unusually high or low, contact your healthcare professional immediately.
- If you are experiencing symptoms that are not consistent with your blood glucose test results and you have made sure to follow all instructions of this manual, contact your healthcare professional immediately.

Please use RIGHTEST Control Solution GC570 tested with RIGHTEST ALPHA Blood Glucose Monitoring System under Control Solution Mode. If the test result is within the Control Solution Range printed on the strip vial label, the RIGHTEST ALPHA Blood Glucose Monitoring System passes Quality Control Test. That means your RIGHTEST ALPHA Blood Glucose Monitoring System is working correctly.

Control Solution Range:



Example of Control Solution Range printed on your test strip vial label.

When could a Quality Control Test be performed ?

Whenever you want to check if your system is working properly or not.

- Whenever you want to practice testing and check correct procedure.
- To prepare for your initial blood glucose test.
- To check the RIGHTEST ALPHA Test Strip when you open a new vial of strips.
- To check your RIGHTEST ALPHA Meter after it has been dropped, damaged or exposed to liquids.
- When you suspect that your test results are inaccurate, or if your test results are not consistent with the way you feel.

Quality Control Test

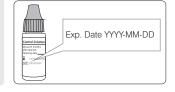
Quality Control Test

The possible reasons your RIGHTEST Control Solution results are out of the range :

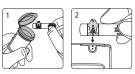
- Your RIGHTEST Control Solution has expired or has been opened more than 3 months.
- You left the cap of the tst strip vial or the control solution opened for a long time.
- You didn't perform the test procedure correctly.
- Malfunction of the meter or the test strip.

If Control Solution results are out of range, your Bionime BGMS may not be working properly. Repeat the Quality Control Test. If your RIGHTEST Control Solution results are still out of range, STOP using the BGMS to test your blood glucose and contact your Bionime Customer service.

Each time you open a new bottle of RIGHTEST Control Solution, write the opening date on the label. RIGHTEST Control Solution is good for 3 months after opened, or until the expiration date printed on the label, whichever comes first. Example of Expiration Date:

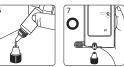


- 1. Take one test strip from vial and close the vial cap immediately.
- 2. Insert the strip into the test strip port of the Meter with the view window facing up.
- 3. While the blood drop symbol flashing, press and hold the main button for over 3 seconds until the " *CS* " symbol appears.
- 4. You will see blinking " " symbol and " *CS* " symbol on the screen, prompting you to apply Control Solution.
- 5. Gently invert the bottle of RIGHTEST Control Solution several times, to mix it thoroughly before use.
- 6. Place a drop of Control Solution on the top of the cap.
- 7. Gently touch sample entry of the strip with the Control Solution on the top of the cap.
- 8. When you hear a beep (if volume is turned on) please wait for the test result. The screen will display the countdown number from 5.



Performing a Quality Control Test







Performing a Quality Control Test

- 9. Close the control solution cap immediately after use, and make sure to close it tightly
- 10. The Control Solution result appears. Compare your Quality Control Test result to the Control Solution Range printed on the test strip vial label.

- Your Control Solution results will not be calculated for average reading but still can be recalled. The Control Solution Test result will be shown with " *cs* " symbol on the screen.
- Our suggestion environment for Control Solution Test is 15 40°C.
- Before " > " and " *CS* " appears, please don't touch the Control Solution to the sample entry on strip because the meter is still in an internal check. If you do so, the meter will show " > "
- and "*Error*", and be accompanied by beeps (if volume is turned on)
 Don't drip the Control Solution to sample entry of the strip directly, doing so may cause the contamination of the control solution or meter.
 Don't touch the tip of the control solution bottle. If you have touched it, please clean up with water.



CLOSE

Indirect transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) during the delivery of healthcare services has been increasingly reported. Persons using blood glucose monitoring systems have been identified as one risk group due to sharing of lancets, lancing devices, and blood glucose meters.

The cleaning procedure is to remove dust, blood and body fluid from the surface and should be performed whenever the meter or lancing device is visibly dirty. The disinfecting procedure is necessary to kill pathogens such as HIV, HBV and HCV on the device.

NOTE: The cleaning procedure can only remove visible contaminates from surfaces. Only the disinfecting procedure can eliminate non-visible pathogens.

If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be decontaminated prior to use by the second person.

The following disinfecting wipe has been tested and may be used to clean and disinfect the meter and lancing device.

CAVIWIPES DISINFECTING TOWELETTES, manufacturer: Metrex. It is with Isopropanol as the active ingredient, have been shown to be safe for use with the meter and lancing device.

Maintain the products

Maintain the products

Maintaining

Keep your meter and test strip free of dust, water or any other liquid. Store the meter in the carrying case when not in use. If your meter is dropped or damaged, perform a quality control test with the control solution before performing a blood glucose test.

Maintain the products

Cleaning and Disinfecting frequency: at least once a week. To clean the meter:

 Thoroughly wipe the entire surface of the meter with disinfecting wipes listed above to clean any possible dirt, dust, blood and other body fluids.

To disinfect the meter:

- 2. Take another disinfecting wipe and wipe the meter thoroughly (Note: All blood and body fluids should be cleaned from surface before performing the disinfecting procedure).
- 3. Allow the surface to remain wet for 2 minute.
- 4. Allow to air dry.





// NOTE

- Clean and disinfect the outside of the device only. Do not remove battery cover when cleaning and disinfecting.

Maintain the products

Cleaning and Disinfecting frequency: at least once a week. To clean the lancing device:

1. Thoroughly wipe the entire surface of the lancing device with disinfecting wipes listed above to clean any possible dirt, dust, blood and other body fluids

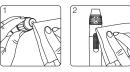
To disinfect the lancing device:

- 2. Take another disinfecting wipe and wipe the Lancing device thoroughly (Note: All blood and body fluids should be cleaned from surface before performing disinfecting procedure).
- 3. Allow the surface to remain wet for 2 minute.

CAUTION

- Users should wash their hands thoroughly with soap and water after handling the meter, lancing device or test strips.

If you have any questions or concerns, please contact your RIGHTEST ALPHA Blood Glucose Monitoring System authorized distributor or contact your local Bionime customer service.





Recalling Test Result and Average

The RIGHTEST ALPHA Meter is able to store 500 test results with time and date automatically. If your meter has stored 500 results, which is the maximum memory of the meter, the newest test result will replace the oldest one. To recall your test memory, start the meter without test strip inserted.

1. Press the main button to switch from the time mode to the Memory screen. First you will see the "mem" symbol on the up per left corner of the display. When you press the right button, the latest result will be displayed. By pressing the right button sequentially former test results will be shown in historical order. You will see the sequence number on the lower right corner and the year on the lower left corner of the display followed by date and time of the measurement.



Note

The right button is for reviewing the tests with sequence number increasing, and the left button is for reviewing tests with sequence number decreasing. The sequence no "1" is the latest result while sequence no "500" is the oldest test result.

2. To finish reviewing memory tests, press main button again, and you will enter the Average screen. By pressing the right button, the display shows "AVG" on the upper right corner of the display and the average value for the actual day. By sequencely pressing the right or left button you will get to the 1-day, 7-days, 14-days, 30-days and 90-days average of your blood glucose values. You will see the number of the calculated days on the lower left corner and the number of the calculated readings on the lower right corner.

Recalling Test Result and Average



3. Non-Averaging set and canceled:

You may select the unwanted or doubtful test results, to exclude them from the average calculation, after your every test. After you finished your test in the test mode, you can exclude the unwanted result. Keep pressing the right butten until you see the symbol "NO AVG" in the top right cornetr of the screen. By keeping the right button pressed and pressing the main button simultaneously to confirm the value as "Non average".

Now this value is flagged by the symbol "NO AVG" in the up per right corner of the screen. If you want to cancel this non-averaging setting, you have to stay in the test mode. First keep pressing the right button until the "NO AVG" symbol changes to "AVG" in the up per right corner of the screen. To confirm this original status you again simultaneously press the main button to confirm the "AVG" status. Now the value will be stored as a regular value and included in the average values.

Recalling Test Result and Average

NOTE

- The average function is related to the time setting. You must set the time right and have enough time intervals on the basis of current inquiry time, to make sure that the average test results will show. Use the 14-day average for example; if your current inquiry time is 1/30, then that you must check that you have tested blood glucose in the past 14 days before 1/30, including today. If not, the 14-day average will show no figure.
- The Non-averaging/re-averaging function only works in the test mode and when you get the value. In the mem mode, you can not perform this action.
- Your Control Solution results will be automatically non-averaged without selecting, but still can be recalled. The Control Solution Test results will show with "CS" symbol under memory screen.
- 4. Quick Searching: If you want to see all values automatically displayed in sequence, first enter the memory mode. Then keep pressing the right or left button for 2 seconds. (right button is for searching the tests the latest value to the oldest one; by using the left button you can scroll from the oldest to the latest one). Anytime you want to stop just release the pressed button. It will stop and display the current displayed value. You can use this way to find a particular reading you want to check.
- 5. Reading right after test: If you just finish the test, press the main button to enter the mem (memory) screen and review the latest test result.



PRECAUTION

- You have to set the time and date to activate the average function. - The " L a " , " H " results, Control Solution results and test results tested under abnormal temperature < 10° C (50°F), > 40°C (104°F) will be excluded from average calculations.

Error messages and Trouble shooting

- **Er1** The inserted test strip has been used or damp. Please use a new test strip from vial.
- **Er2** Meter has malfunctioned. Reinstall the batteries and do the Quality Control Test to check if the meter works properly.
- **Er3** Signal transmission is disrupted, repeat the test with a new test strip.
- **Er4** Applied blood volume is insufficient, please repeat the test with a new test strip.

Above, if error screen still appears contact your local Bionime Customer Service.



Er3 (Er4)

Error messages and Trouble shooting

Battery Error

- 1. The " I symbol is blinking when the battery power is low. Please change the meter battery as soon as you can. You can still do the test.
- 2. The " I and " Error " symbols are blinking when the battery is too low. Meter can not do the strip test. Please change the meter battery immediately.



```

1a)



# **Error messages and Trouble shooting**

#### Temperature Error

In order to get accurate test result, perform testing between 10 - 40°C (50 - 104°F).

When the ambient temperature is 0 - 9°C (32 - 49°F) or 41 - 50°C (105 - 122°F) 1a) the " - " warning symbol will be blinking (1a), you still can do the test but the test result is only for reference, because the test result under these ranges of temperature might not be correct. In the memory screen this value will be flagged with " - " symbol (1b). Repeat the test at an area with temperature between operating range (10 - 40°C or 50 - 104°F).



m

mem

1b) I

- If the RIGHTEST ALPHA Blood Glucose Meter and Test Strips are exposed to a substantial change in temperature, or out of recommended operating temperature - below 10°C (50°F) or above 40°C (104°F) - move them back to recommended condition and wait at least 30 minutes before testing again.
- 3. When the temperature is below 0°C (32°F) or over 50°C (122°F), Meter can not do the test and the "*Error* " symbol will blink with " " symbol displaying on screen in this condition. Please move the meter to environment with temperature between 10 40°C (50 104°F) and repeat the test after 30 minutes.

Error -

2021

# **Error messages and Trouble shooting**

#### Sampling Error

Please don't apply the blood drop to the sample entry of the strip before the meter displays " > ". If you do so, the meter will display " *Error* " and " > " accompanied by beeps (if volume is turned on). Please discard the test strip and repeat the test with a new test strip.



#### Meter Malfunction

If the meter can not be started, please follow the steps below:

- 1. Open the battery cover, remove the batteries.
- Wait for 5 minutes and insert the batteries as described "Meter activation and Battery change" on page 16 - 17.

The meter should be working normally after finishing above steps. If not, please contact your local Bionime customer service.

# Specification

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# Specification

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| Measurement Technology      | Oxidase Electrochemical Sensor                                                                           |
|-----------------------------|----------------------------------------------------------------------------------------------------------|
| Measurement Calibration     | Plasma                                                                                                   |
| Measuring Range             | 10 - 600 mg/dL (0.6 - 33.3 mmol/L)                                                                       |
| Test Time                   | 5 seconds                                                                                                |
| Memory Capacity             | 500 blood glucose test results with date and time                                                        |
| Power Saving                | Turn off automatically 2 minutes after last user action / Press the " $\bigcirc$ " button for 3 seconds. |
| Operating Temperature       | 10 - 40°C (50 - 104°F)                                                                                   |
| Operating Relative Humidity | 10 - 90%                                                                                                 |
| Power Supply                | 1 CR2032 battery                                                                                         |
| Meter Battery Life          | About 1,000 tests                                                                                        |
|                             |                                                                                                          |

| Meter Dimension                                | 90.6 mm x 46 mm x 16.5 mm            |
|------------------------------------------------|--------------------------------------|
| Meter Weight                                   | $53.0 \pm 5$ g with battery          |
| Monitor                                        | LCD display                          |
| Display Area                                   | 46.6 mm x 33 mm                      |
| Meter Storage Conditions                       | -10 - 60°C (14 - 140°F)              |
| Sample                                         |                                      |
| Minimum Sample Volume                          | Refer to RIGHTEST ALPHA Strip insert |
| Hematocrit                                     |                                      |
| Test Strip Storage / Transportation Conditions |                                      |

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- I

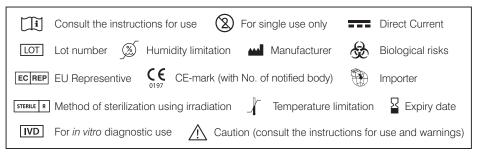
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## Limitations

- RIGHTEST ALPHA Blood Glucose Monitoring System is not intended for serum or plasma test
- Inaccurate test results may be obtained at high altitude more than about 3,048 meters (10,000 feet) above sea level.
- Test results may be falsely low if the patient is severely dehydrated, in shock, or in a hyperosmolar state (with or without ketosis).
- Patients going through oxygen therapy may yield falsely low results.
- These test strips should not be used with meters to test critically ill patients or neonates.
- The blood glucose test result may be affected by high blood concentration of interference ingredients, if you need more detail information about interference ingredients, please see RIGHTEST ALPHA Test Strip Insert.
- Alternative site testing (AST) should only be performed during steady-state times (when glucose is not changing rapidly).
- Please refer to the (Alternative site testing (AST)) chapter if you want to test on palm or forearm.
- DO NOT test on alternative site (palm, forearm) if you are testing for insulin dose calculations or for Continuous Glucose Monitoring (CGM) devices calibration, or hypoglycemia (Low blood glucose).
- To avoid potential electromagnetic or other interference, keep meter away from electromagnetic radiation sources such as X-ray or MRI.
- Keep your meter away from dust, water or any liquid.

We sincerely like to provide complete, considerate services to our customers. Please review all the instructions to make sure you are performing the steps correctly. If you have any questions or in case of problems with the RIGHTEST ALPHA products, please contact your local Bionime customer service.

#### Description of used symbols



**Customer Service** 

# Warranty

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The manufacturer warrants that your RIGHTEST ALPHA Meter will be free from defects in materials and workmanship for five years from the date of purchase. This warranty does not apply to the performance of a RIGHTEST ALPHA Meter that has been altered, misused, tampered with or abused in any way. \_

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

Please complete and return the enclosed warranty card to your local Bionime affiliate.

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