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BLOOD GLUCOSE MONITORING SYSTEM

Prolife PM200

EN Instruction manual

TABLE OF CONTENTS

1 Introduction 4
1.1 About Blood Glucose Monitoring System Prolife PM200 4
1.2 Intended Use 5
1.3 Package of Prolife PM200 BGMS Kit 6
2 Prolife PM200 Meter 8
2.1 Caution 11
3 Prolife Test Strip PT200 13
4 Meter activation and Battery change 15
5 Setting Up Your Meter: Setting the Time, Volume and Date 16
6 Turning On/Off meter 19
7 Testing Procedure 19
7.1 Performing a Blood Test 19
7.2 Alternative Site Testing (AST) 23
7.3 View window appearance 24
7.4 «Lo» and «Hi» readings 25

7.5 Quality Control* 26
7.6 Quality Control Test* 27
7.7 Performing a Quality Control Test* 27
8 Recalling test results 29
8.1 Recalling Test Result and Average 29
9 Maintain the Products 32
10 Error Messages and Trouble Shooting 35
11 Specification 37
12 Limitations 38
13 Customer Service 40
14 Description of used symbols 40
15 Warranty 41

1 INTRODUCTION

1.1. ABOUT BLOOD GLUCOSE MONITORING SYSTEM PROLIFE PM200

Thank you for choosing the Blood Glucose Monitoring System **Prolife PM200 (BGMS)**.

Please read this manual thoroughly before testing. It provides all information you need to use the product.

The Blood Glucose Monitoring Meter **Prolife PM200** must only be used with **Prolife Test Strip PT200 and Control Solution Prolife PC200***.

Please only purchase test strips in the same country you purchased your meter. Use of test strips from different countries might get deviated test results under such circumstance.

⚠ NOTE

Further such terms for short are used:

The Blood Glucose Monitoring System Prolife PM200 – **Prolife PM200 BGMS**.

Blood Glucose Meter Prolife PM200 – **Prolife PM200 Meter**.

Blood Glucose Monitoring System Prolife Test Strip PT200 – **Prolife Test Strip PT200**.

It is recommended to monitor blood glucose regularly. **Prolife PM200 BGMS** is accurate and easyto-use and is thus your reliable assitant for diabetes management.

Prolife PM200 BGMS is manufactured by BIONIME Corporation.

If you have any question or concern, please contact your local Prolife Customer Service.

1.2. INTENDED USE

Prolife PM200 BGMS is intended *in vitro* diagnostic use only (outside the body). The testing result is calibrated to plasma equivalent with whole blood from capillary. Capillary whole blood can sample from the fingertip, palm or forearm. You may consult your healthcare professional for instructions on how to use the system correctly. Our customer support staff are also available to assist you.

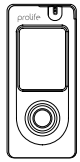
1.3. PACKAGE OF PROLIFE PM200 BGMS

Your **Blood Glucose Monitoring System Prolife PM200** consists of several items. Please identify each item of your system and learn what they're called and how they're used. These items are included in your **Blood Glucose Monitoring System Prolife PM200.**

1. **Prolife PM200 Meter** (with 1 CR2032 battery installed)
2. **Prolife Test Strip PT200** (0/25/50 pcs) *
3. Getting Started Guide
4. User Manual **Prolife PM200**
5. **Prolife Test Strip PT200** Package Insert *
6. **Lancing Device Prolife GD500***
7. Clear Cap *
8. Disposable lancets Prolife GL300 *
9. Instructions for the lancing device *
10. **Control Solution Prolife PC200** *
11. Control Solution Package Insert *
12. Warranty Card *
13. Carrying Case *

Different packages have different bundled items. Some of packages might not include « * » items.

1



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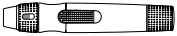

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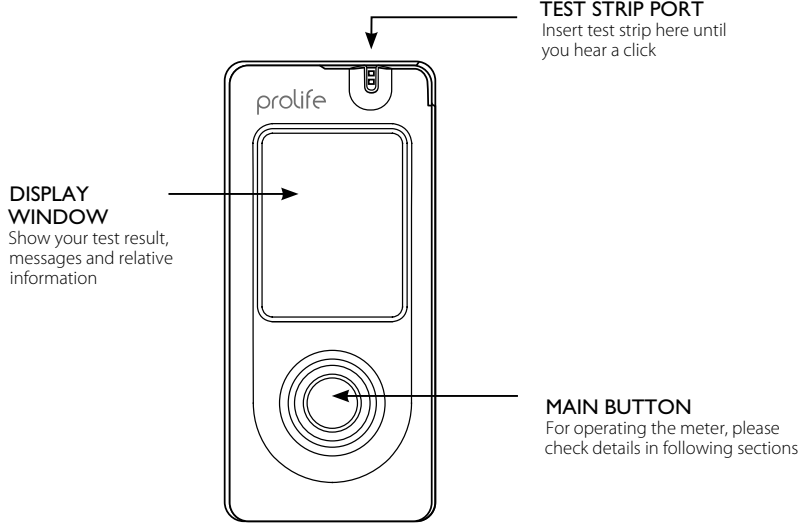
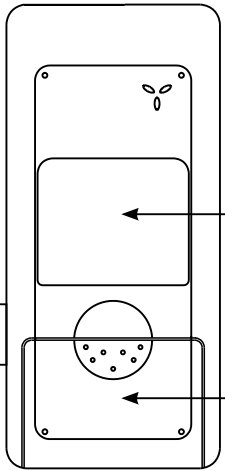
**Different packages have different bundled items. Some of packages might not include « * » items.*

2 PROLIFE PM 200METER

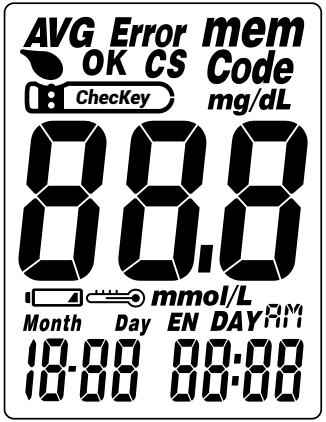




PLASTIC TAPE
Pull it off to activate meter. (If time and date of your meter has been set in advance, the plastic tape will be removed. Hence, please discard this step)

METER LABEL

BATTERY COVER
Slide cover to change battery

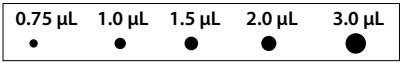


mem	Indicates a test result stored in memory		Tell when to apply the blood sample
No character « **AVG** »	Indicates a test result, not joining into the Average function of this meter		Test strip
AVG	Indicates with the average result	**Error**	Appears after you insert test strip into meter
CS	Indicates a control solution test result	Month Day 10:00	Current date under time mode or Testing date under memory mode
mg/dL **mmol/L**	Unit of test result		Indicates if the environmental temperature is exceeded during testing
88.8	Test result	AM PM	Indicates the time in 12H format
	Warns when the battery is low or must be replaced	00:00	Current time under time mode or Testing time under memory mode
OK Code ChecKey EN DAY		Manufacturing use only	

2.1 CAUTION (PAGE TITLE)

- Before using **Prolife PM200 BGMS** to test your blood glucose, please read all of the info and conduct all of the tests including the quality control test (Refer to page xx).
- Please perform the quality control test regularly to make sure the test results are fine.
- **Prolife PM200 Meter** can only be used with **Prolife Test Strip PT200.** Other brands' test strips should not be used under any circumstances. The use of other brands' strips may give inaccurate results.
- If **Prolife PM200 Meter** or **Prolife Test Strips PT200** are exposed to temperature environments out of range for the meter – below 50 °F (10 °C) or above 104 °F (40 °C) – please wait 5-30 minutes before testing again.
- To protect our environment, please follow local environmental regulations when disposing of batteries, strips and lancets.
- To avoid potential electromagnetic or other interference, keep meter away from electromagnetic radiation sources such as X-ray or MRI.
- Avoid contact with dripping or splashing liquids.
- Check the blood sample size to test in the Test strip insert.
- The minimum blood sample size for testing is 0.75 µL: (•).

Sample Size Example



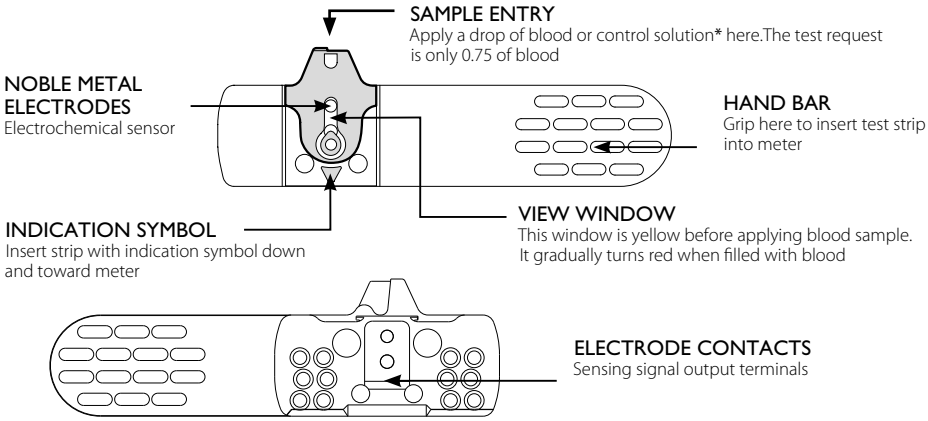
Please take a minimum of 0.75 µL to do the test on blood glucose monitoring system. Blood sample size above 3.0 µL might contaminate the meter. A blood sample size below 0.75 µL will cause Er4. In this case, repeat the test with a new test strip.

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 32.
- Users should wash their hands wholly with soap and water before and after touching the meter, lancing device, or test strips.
- The Meter and Lancing Device are for single patient use. Do not share them with anyone including family members.

3 PROLIFE TEST STRIP PT200

The **Prolife PM200 Meter** must only be used with **Prolife Test Strip PT200** and **Control Solution PC200***.
The application of other Test Strips or control solutions* can lead to incorrect results.



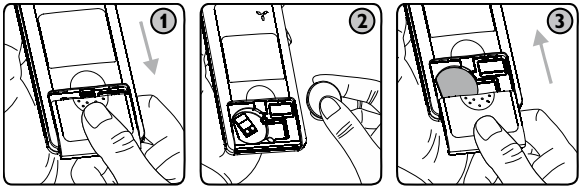
PRECAUTION

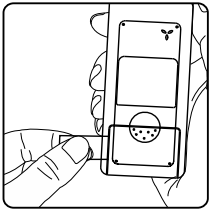
- Close the vial rapidly after taking out a test strip.
- Do not reuse test strips.
- Do not use expired test strips.
- Write the date of first opening a new test strip vial on the vial.
- Use each test strip immediately after removing from the vial.
- For detailed information as validity period after open and storage environment, please refer to **Prolife Test Strip PT200** Insert.

4 METER ACTIVATION AND BATTERY CHANGE

Your meter comes with one CR2032, 3 volt, batteries installed. New battery 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. Press and push battery cover to open.
2. Install the batteries. Be sure to put batteries in correct direction.
3. Slide the battery cover back until it snaps into place.
4. The meter performs a self test.
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.





NOTE

Before using it, please pull off the plastic tape and press the main button to activate the meter.

PRECAUTION

Please follow the local regulation and discard a used battery properly.

5 SETTING UP YOUR METER: SETTING THE TIME, VOLUME AND DATE

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.

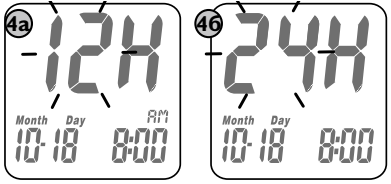
2. With Battery inserted.

   Press the main button first to turn on the meter. Then press and hold the main button for 7 seconds 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.

1. Year setting
   With the year format blinking, press the Main 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 Main button until the current month appears. Then press the Main button to confirm it and move to Day setting.
3. Day setting
   With the day blinking, press the Main button until the current day appears. Then press the Main button to confirm it and move to Time format setting.
4. Time format 12/24 H selection
   With the time format blinking, press the Main button to adjust it. Then press the Main button to confirm it and move to hours setting.
5. Hour setting
   With the hour blinking, press the Main 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 Main button to adjust it. Then press the Main button to confirm it. Then it will move to volume setting.
7. Volume setting
   With the volume blinking, press the Main button to turn it on or off. Then press the Main button to confirm and move to measurement of unit setting.
8. Setting the Unit of Measurement
   With milligrams per deciliter (mg/dL) or millimole per liter (mmol/L) blinking, press the Main button to switch. Then press the main button to confirm it and finish the settings.

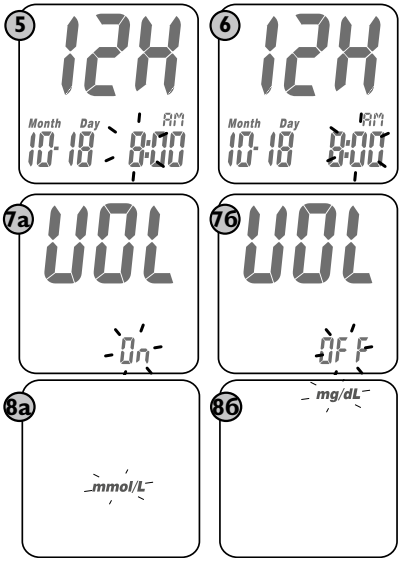


9. Ending setting

After measurement of unit settings, 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 you do not do any settings of meter for over 2 minutes, the meter will leave setting mode and power off automatically.
- Your **Prolife PM200 Meter** default is set according to your local preference.



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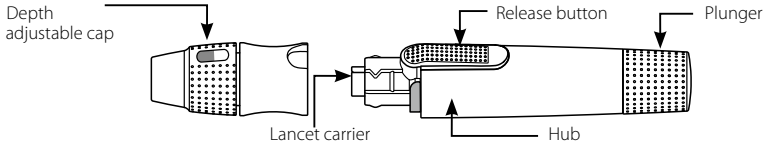
6 TURNING ON/OFF METER

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.

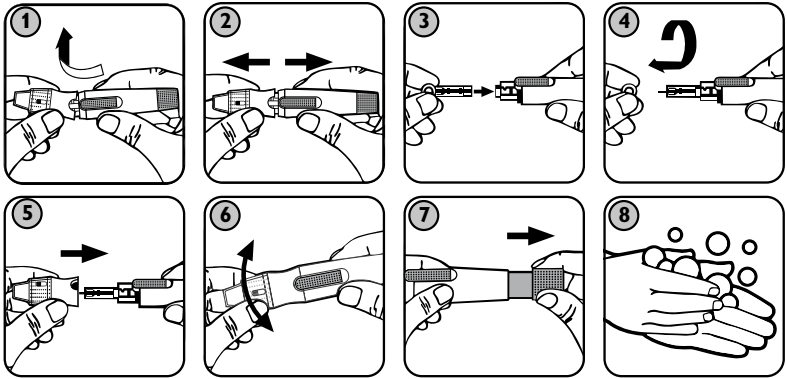
7 TESTING PROCEDURE



7.1 PERFORMING A BLOOD TEST

1. 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.
2. Pull the cap and hub off in opposite directions, remove the cap.
3. Insert a new disposable lancet firmly into lancet carrier.

4. Twist off and set aside the protective cover of the disposable lancet.
5. Replace the depth adjustable cap.
6. 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: for soft or thin skin, for average skin, for thick or calloused skin.
7. 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.

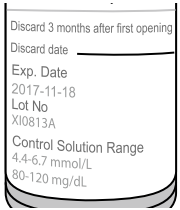


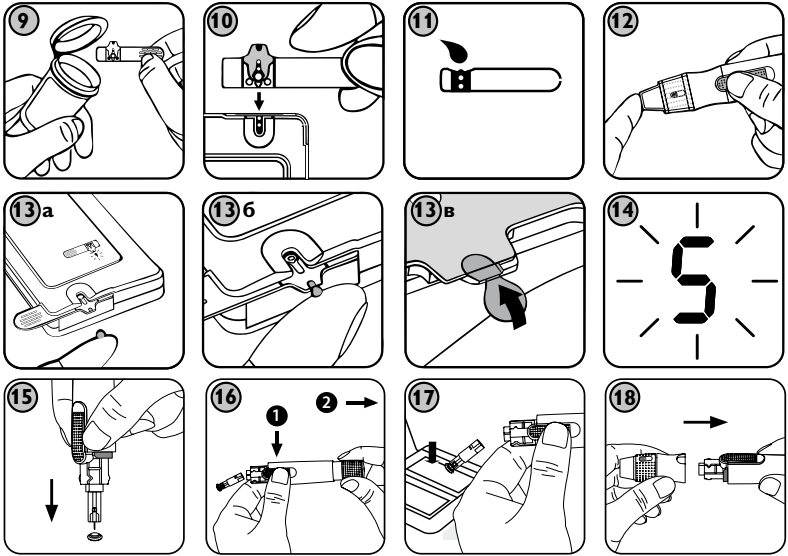
8. Wash your hands with warm soapy water and dry thoroughly.
9. Take one strip from the vial. Re-cap the vial cap immediately.
10. Insert the strip into the strip port of the meter with the indication symbol facing down. The meter confirms the insertion of the strip with a beep (if volume is turned on).
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 totally filled with blood. If the View Window is not totally filled with blood or the test does 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.
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 and strip into an appropriate puncture-proof or biohazard container.
18. Replace the depth adjustable cap after finishing the test.

PRECAUTION

⚠ 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.

- Record the date of opening a new test strip vial for the first time. Discard the vial of test strips after 12 months from opening.
- 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.





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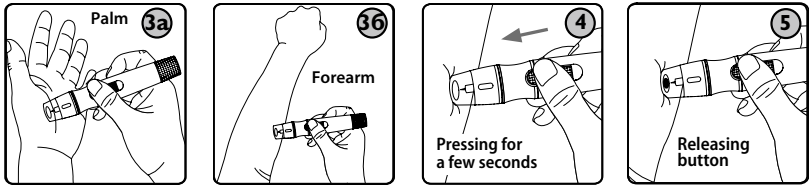
7.2 ALTERNATIVE SITE TESTING

Alternative site testing-palm or forearm blood sampling

1. Choose Clear Cap and follow step 1-5 on page 18-19.
2. Massage the puncture area of palm or forearm for a few seconds.
3. 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.
5. 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 20 to complete the test and discard the used disposable lancet.

⚠ PRECAUTION

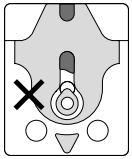
- Consult your healthcare professional before sampling from your palm or forearm.
- The glucose test results of blood samples from palm or forearm might be varied in conditions which glucose changing rapidly as drinking, eating, medication or exercise. In these cases, only fingertip blood should be used.

- Fingertip samples can show the rapid change of glucose faster than palm or forearm samples.
- DO NOT test on the palm or forearm if you are testing for hypoglycemia (Low blood glucose).
- The forearm or palm blood flow may be slower than fingertip, we recommend using Prolife GD500 lancing device with Clear Cap for the sampling.
- DO NOT test on the palm or forearm if you are testing for insulin dose calculations or hypoglycemia (Low blood glucose).
- Palm or forearm result should not be used to calibrate continuous glucose monitors (CGMs).

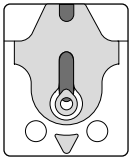
7.3 VIEW WINDOW APPEARANCE

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

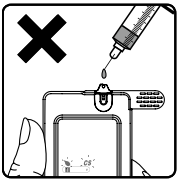


Enough blood sample



⚠ PRECAUTION

- 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.



7.4 «LO» AND «HI» READINGS

1. The **Prolife PM200 Meter** displays results between 10 and 600 mg/dL (0.6 and 33.3 mmol/L). If your test result is below 10 mg/dL (0.6 mmol/L), «Lo» will appear on the screen. Please repeat your test with by a new test strip. If you still get «Lo» result, you should immediately contact your healthcare professional.
2. If your test result is above the high end of the system's detection range 600 mg/dL (33.3 mmol/L), «Hi» will appear on the screen. Please repeat your test with a new test strip. If you still get «Hi» result, you should immediately contact your healthcare professional.

⚠ NOTE

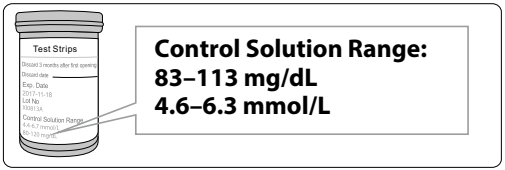
- If your blood glucose result is unusually high or low, or if you question your testing results, repeat the test with a new test strip. If the test result still remains unusually high or low, contact your healthcare professional immediately.
- If you are experiencing symptoms that are not consistent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

7.5 QUALITY CONTROL TEST*

Please use **Control Solution PC200*** tested with **Prolife PM200 BGMS** under Control Solution Mode. If the test result is within the Control Solution Range* printed on the strip vial label, the **Prolife PM200 BGMS** passes Quality Control Test. That means your **Prolife PM200 BGMS** is working correctly.

Control Solution Range

When should a Quality Control Test be performed?



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

- Whenever you want to check if your system is working properly or not.
- Whenever you want to practice testing and check correct procedure.
- To check your **Prolife PM200 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.
- Whenever you want to practice testing and check correct procedure.
- To prepare for your initial blood glucose test.

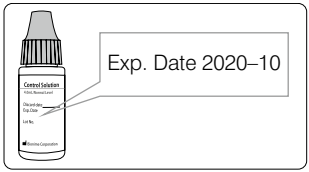
**Different packages have different bundled items. Some of packages might not include « * » items.*

7.6 QUALITY CONTROL TEST*

The possible reasons your Quality Control Test are out of the range:

1. Your Control Solution* has expired or has been opened 3 months ago.
2. Your test strip has expired.
3. You left the cap of the tst strip vial opened or the control solution* off for a long time.
4. You didn't perform the test procedure correctly.
5. Malfunction of the meter or the test strip.

If Control Solution* results are out of range, your **Prolife PM200 BGMS** may not be working properly. Repeat the Quality Control Test. If your Control Solution* results outside the range still exist, do not use the **BGMS** to test your blood glucose and contact your Prolife Customer service.



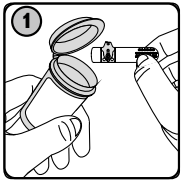
⚠ PRECAUTION

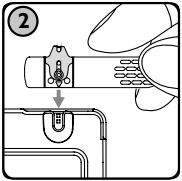
Each time you open a new bottle of Control Solution*, write the discard date on the label. Control Solution* is good for 3 months after opening the bottle, or until the expiration date printed on the label, whichever comes first.

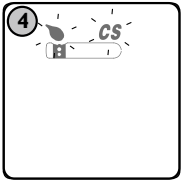
7.7 PERFORMING A QUALITY CONTROL TEST*

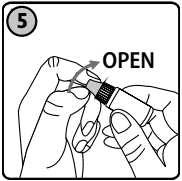
1. Take one test strip from vial and Re-cap the vial cap immediately.
2. Insert the test strip with view window, facing down, into test strip port.
3. While the blood drop symbol flashing, press and hold the main button for over 3 seconds until the « **CS** » symbol appears.

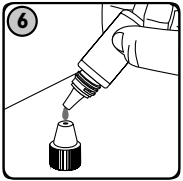
**Different packages have different bundled items. Some of packages might not include « * » items.*

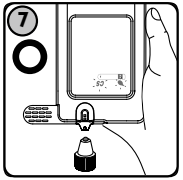


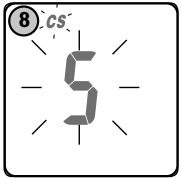


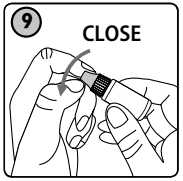










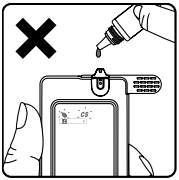


4. You will see blinking « », symbol and « **cs** », symbol on the screen, prompting you to apply Control Solution*.
5. Shake the bottle of Control Solution* well before opening the cap. Then open the bottle and put the cap on the table.
6. Drip a drop of Control Solution* on the top of the cap.
7. Gently 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.
9. Tightly replace the cap on the Control Solution* bottle.
10. The Control Solution* result appears. Compare your Quality Control Test result to the Control Solution. Range printed on the test strip vial label.

**Different packages have different bundled items. Some of packages might not include « * » items.*

⚠ PRECAUTION

- Your Control Solution* results will not be calculated for average reading but still can be recalled. The Quality Control Test result will be shown with « **CS** » symbol on the screen.
- Our suggestion environment for Quality Control 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** ». Accompanied by beeps (if volume is turned on).
- Don't drip the Control Solution* to sample entry of the strip directly. The reagent on strip might be sucked into the bottle of Control Solution* and might cause the degeneration of Control Solution*. Doing this might contaminate the meter via the test strip port as well.
- Don't touch the tip of the control solution* bottle. If you have touched it, please clean up with water.



8 RECALLING TEST RESULTS

8.1 RECALLING TEST RESULT AND AVERAGE

The Prolife PM200 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 right corner of the display.

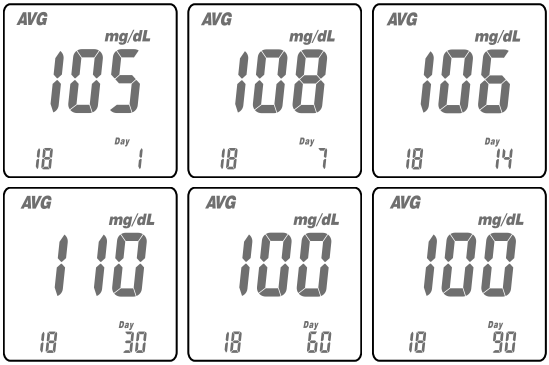
**Different packages have different bundled items. Some of packages might not include « * » items.*

When you press the main button, the latest result will be displayed. By pressing the main 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 main button is for reviewing the tests with sequence number increasing.
The sequence no «1» is the latest result while sequence no «500» is the oldest test result.

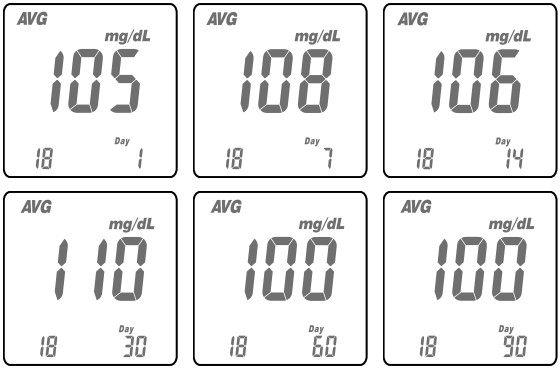
2. To finish reviewing memory tests, press main button again, and you will enter the Average screen. By pressing the main button, the display shows «AVG» on the upper left corner of the display and the average value for the actual day. By sequencely pressing the main button you will get to the 1-day, 7-days, 14-days, 30-days, 60-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.



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-days 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.

3. 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.



NOTE

- You have to set the time and date to activate the average function.
- The «Lo» and «Hi», results, the Control Solution* results and the test result made out of normal temperature range (<10 °C, >40 °C) are not calculated in the average.

9 MAINTAIN THE PRODUCTS

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

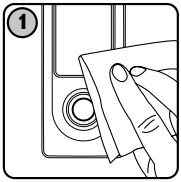
The cleaning procedure can only remove visible contaminates from surfaces. Only the disinfecting procedure can eliminate non-visible pathogens.

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.

Cleaning and Disinfecting frequency: at least once a week.

Maintaining

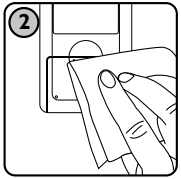
Keep your meter and test strip free of dust, water or any other liquid. Store the meter in the carrying case when not in use. If your meter is dropped or damaged, perform a quality control test with the control solution* before performing a blood glucose test.

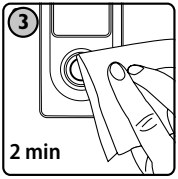


To clean the meter:

1. 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 to air dry.

⚠ NOTE

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

Cleaning and Disinfecting frequency: at least once a week.

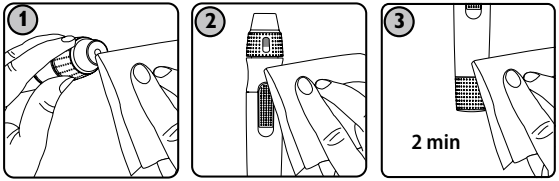
**Different packages have different bundled items. Some of packages might not include « * » items.*

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).



CAUTION

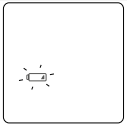
- Users should wash their hands thoroughly with soap and water after handling the meter, lancing device or test strips.
- If you have any questions or concerns, please contact your **Prolife PM200 BGMS** authorized distributor or contact your local Prolife customer service.

10 ERROR MESSAGES AND TROUBLE SHOOTING

Problem	Possible causes
	The inserted test strip has been used or damaged. Please use a new test strip from vial
	Meter has malfunctioned. Reinstall the batteries to check if the meter works properly
	Signal transmission is disrupted, repeat the test with a new test strip
	Applied blood volume is insufficient, please repeat the test with a new test strip

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

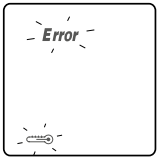
Battery Error

The « [▮] » symbol is blinking	The battery power is low. Please change the meter battery as soon as you can. You can still do the test	1a  1b 
The « [▮] » and « ***Error*** ». Symbols are blinking	The battery is too low. Meter can not do the strip test. Please change the meter battery immediately	2 

Temperature Error

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

When the temperature is below 10 °C (50 °F) or over 40 °C (104 °F), the meter will not function and the « ***Error*** » and « [🌡] » symbol will blink.
If the Blood Glucose Meter and Test Strips are exposed to out-range temperature, please wait 30 minutes before measurement.



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.
2. Wait for 5 minutes and insert the batteries as described «Meter activation and Battery change».

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

11 SPECIFICATION

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 « ◯ » 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, (mm)	95 x 43.8 x 13
Meter Weight, (g)	43 ± 5 (with battery)
Monitor	LCD display
Display Area, (mm)	39 x 38
Storage and Transportation	-10 to +60 °C (14–140 °F)
Sample	Refer to Strip insert Prolife PT200
Minimum Sample Volume	
Hematocrit	
Test Strip Storage/Transportation Conditions	

12 LIMITATION

- **Prolife PM200 BGMS** is intended for self-testing.
- **Prolife PM200 BGMS** can only use with capillary whole blood samples.

- **Prolife PM200 BGMS** is for over the counter use and single patient use only. It is Not for use on critically ill patients, it is Not for use on neonates either. Not for screening or diagnosis of diabetes.
- The blood glucose result of the meter may be much lower than «true glucose levels» in the hyperglycemic-hyperosmolar state, with or without ketosis.
- Low blood sugar (hypoglycemia), in some cases, diabetes can trigger low blood pressure.
- Test results may be falsely low if the patient is severely hypotensive, severely dehydrated, in shock, or in a hyperosmolar state (with or without ketosis).
- DO NOT use at altitudes greater than 10,000 feet (3,048 meters).
- DO NOT use the results from alternative site testing (palm, forearm) to calibrate Continuous Glucose
- Monitoring (CGM) devices.
- DO NOT test on the alternative site (palm, forearm) if you are testing for insulin dose calculations or hypoglycemia (Low blood glucose).
- DO NOT test on the alternative site (palm, forearm) when glucose is changing rapidly (senarios: after drinking, after meal, after exercise).
- **Prolife Test Strip PT200** will be interfered for hematocrit range and other substances, please refer to Strip insert for detailed infromation.

⚠ NOTE

- DO NOT use this meter close to source of strong electromagnetic radiation, to avoid interference with proper operation.
- Suggest to keep meter free of dust, water or any liquid.

13 CUSTOMER SERVICE

We sincerely like to provide complete 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 **Prolife PM200 BGMS**, please contact your local Prolife customer service.

14 DESCRIPTION OF USED SYMBOLS

Symbols	Description
	Biological risks
REF	Reference number
EC REP	EC Representive
⎓	Direct current
STERILE R	Method of sterilization using irradiation
	Manufacturer
LOT	Lot number
CE	CE Mark

Symbol	Description
	Expiry date
IVD	For *in vitro* diagnostic use
	Temperature limitation
	For single use only
	Consult the instruction for use
CE 0197	CE-mark (with No. of notified body)
	Humidity limitation

15 WARRANTY

The manufacturer warrants that your **Prolife PM200 Meter** will be free from manufacturing defects for five years from the date of purchase. The service life of the device is 5 years.

This warranty does not apply to the performance of a **Prolife PM200 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 Prolife customer service.

If the **Prolife PM200 Meter** and strip are exposed to a high temperature difference, please wait 30 minutes before measurement.

The date of mass production is placed on the package.

⚠ NOTE

During blood glucose measurement, the **Prolife PM200 Meter** itself may come into contact with blood. Used **Prolife PM200 Meter** therefore carry a risk of infection. Please dispose of your used **Prolife PM200 Meter** after removing the battery-according to the regulations applicable in your country. For information about correct disposal, please contact your local council and authority.

BIONIME

Manufacturer/Изготовитель:
Bionime Corporation
No. 100, Sec. 2, Daqing St., South Dist., Taichung City 40242, Taiwan, China.

EC REP Authorized Representative in the EU:
Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands.

Manufacturer of lancet:
Tianjin Huahong Technology Co., Ltd.
A01, Plant B, No. 278, Hangkong Road, Tianjin Pilot Free Trade Zone
(Air Port Industrial Park) 300308 Tianjin, China.

EC REP Shanghai International Holding Corp.:
GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany.

EAC CE 0197

prolife