125x70 mm

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Blood Glucose Monitoring System





USER'S MANUAL

Rightest[™] GM720

Preface

Thank you for choosing the *Rightest*[™] blood glucose monitoring system GM720. Please read this manual thoroughly before testing your blood glucose. It provides all information you need to use the product. The *Rightest*[™] blood glucose meter GM720 must only be used with *Rightest*[™] blood glucose test strips GS720 and *Rightest*[™] control solution GC700. The use of other test strips or control solutions may lead to incorrect test results.

It is recommended that the blood glucose should be monitored regularly. The *Rightest*[™] blood glucose monitoring system GM720 is accurate and easy to use, and is therefore your reliable assistant for diabetes management.

Preface

The *Rightest*[™] lancing device GD720 and the *Rightest*[™]lancets are intended for patient self-monitoring by an individual. They must not be used on more than one person due to the risk of cross-infection.

The *Rightest*™ blood glucose monitoring system GM720 is manufactured and distributed by Bionime Corporation. If you have any questions or concerns, please contact your local Bionime customer service.

Intended use

The *Rightest*TM blood glucose monitoring system GM720 is intended for in-vitro (outside the body) diagnostic use for self testing. The coding of the test strips is automatically detected. The test result is plasma equivalent and achieved by using (a) fresh capillary whole blood that may be drawn from the fingertip, palm or forearm, (b) venous whole blood samples, (c) arterial whole blood samples and (d) neonatal whole blood samples. You may consult your health-care professional for instructions on how to use the system correctly. Our customer support staff is available to assist you.

Healthcare professionals may use the *Rightest*[™] blood glucose monitoring system GM720 for surveillance of the blood glucose levels of patients in medical facilities.

Intended use

For a better understanding of this user's manual, hereinafter the *Rightest*TM blood glucose monitoring system GM720 will be referred to as BGMS; the *Rightest*TM blood glucose meter as meter GM720; the *Rightest*TM blood glucose test strips GS720 as test strips; the *Rightest*TM lancing device GD720 as lancing device; the *Rightest*TM lancets as lancets; and the *Rightest*TM control solution GC700 as control solution.

Table of contents

First steps	
■ Rightest™ GM720 package contents	8
■ <i>Rightest</i> ™ blood glucose meter GM720	
■ First start-up	11
How to perform a blood glucose	
measurement	15
How to set a marker	21

Rightest™ GM720 blood glucose meter	
■ Edit marker: how to add/change	
markers of your results	22
Records: recalling test results	27
Averages: recalling average test results	29
Alarm: how to set an alarm	31
Settings: set language	33
Settings: set date	34
Settings: set time	36
Settings: set volume	38
Quality control test	
Rightest ™ control solution GC700	39
Battery	47

Table of contents

Rightest™ GD720 lancing device	
Handling	51
Alternative site testing (AST)	54
Rightest™ GS720 blood glucose test strips	
Handling	58

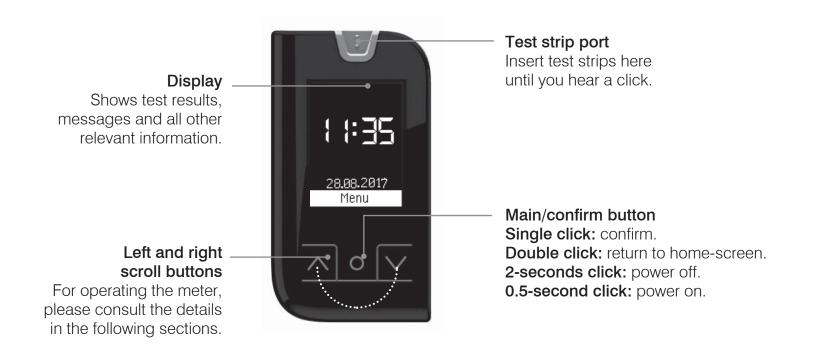
Further informations	
Precautions	61
■ Limitation of the <i>Rightest</i> ™ blood glucose	
meter GM720	63
 Maintenance and cleaning the meter 	64
■ Error messages and trouble shooting	65
Technical specifications	69
■ Disposing of the <i>RightestTM</i> blood glucose r GM720, blood glucose test strips GS720	neter
and lancets	71
Warranty	72
Customer service	73
Manufacturer	75

Rightest[™] GM720 package contents



- 1. **Rightest**[™] blood glucose meter GM720 (with 2 CR2032, 3 volt batteries installed)
- 2. Vial with *Rightest*™blood glucose test strips GS720 (10 pcs)
- 3. *Rightest*™ lancing device GD720
- 4. Disposable *Rightest*™lancets (10 pcs)
- 5. *Rightest*™ GM720 user's manual
- 6. *Rightest*™ GM720 carrying case (not shown)
- 7. Getting Started Guide (not shown)
- 8. Log book (not shown)

Rightest[™] blood glucose meter GM720



Rightest[™] blood glucose meter GM720





Battery cover
Slide cover
downwards to
change batteries.
Instructions
see page 47.

Before you can use the *Rightest*™ GM720 BGMS, you first need to pull out the battery isolation tap and make some settings.



Power on press of for 0.5 seconds.



Select your **language** preference and scroll down to "OK" and press the **O**.



Set the date format.



Switch and confirm with

.







Set the day/month/year. Switch and confirm with **O**.



Set the **time format** (24/12 hour) and confirm with **①**.





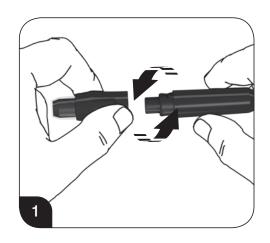
Set the **hour** and **minute**. Switch and confirm with **O**.



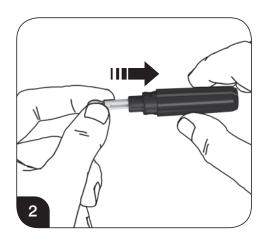
You are now ready to use the *Rightest*TM GM720 BGMS.



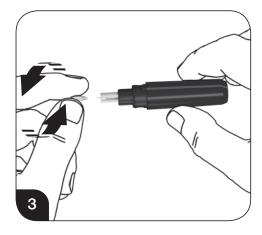
When changing batteries, the start-up procedure may be repeated. Please see page 47 for further instructions to keep settings when changing batteries



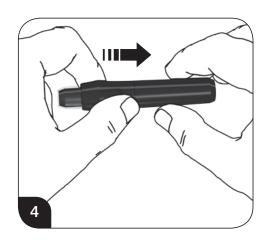
Take off the depth-adjustable cap by turning smoothly in opposite directions.



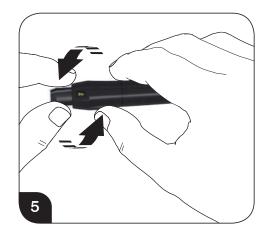
Insert a new disposable lancet firmly into lancet carrier.



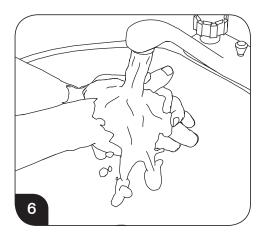
Twist off and set aside the protective cover of the disposable lancet.



Replace the depth-adjustable cap by smoothly turning into lock position.



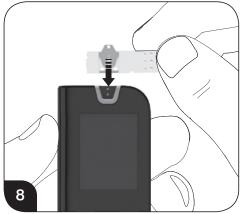
Choose the penetration depth by turning the cap. 1–3 for soft or thin skin; 4–5 for average skin; 6–7 for thick or calloused skin.



Wash and dry your hands.



Take one test strip from the vial and close the cap of the vial immediately.



Insert the test strip into the test strip port on the meter. The meter will automatically turn on.

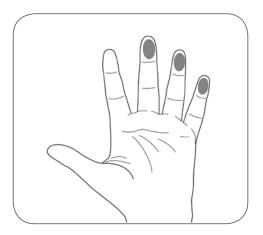




After a short screen and recognizing check, the symbol "Apply blood" will appear.



- 1 Press the security button to unlock the lancing device (keep pressing until pricked).
- 2 Place the finger against the lancing device and press the finger on the cap. The lancing device has an automatic loading and releasing function → no priming necessary.



Recommended sites for obtaining blood.



Gently squeeze your fingertip to get a drop of blood. Apply the blood drop on the edge of the test strip. When the view window is completely filled with blood, you will hear a beep (if the volume of the meter is switched on) and the measurement process starts.

If the view window of the test strip is not completely filled with blood, the measurement will not start. Discard the test strip and repeat the test with a new one.





The "Please wait" symbol will appear for 5 seconds before the test result is displayed. For further information about your test result, please consult your doctor. If your test result is below 10 mg/dL (0.6 mmol/L) , "Lo" will appear on the screen. If your test result is above 600 mg/dL (33.3 mmol/L), "Hi" will appear on the screen. Please repeat your test with a new strip. If you still get a "Lo" or "Hi" result, you should immediately contact healthcare professional.



Remove the test strip from the meter. Please follow your local regulations and discard the used test strip properly.

How to set a marker









For further markers please go to "Edit Markers" under page 22.

The test result is displayed on the screen with time and date in the bottom line. Choose directly between three markers. Choose between the "Before meal" marker, the "After meal" marker and no marker. Confirm with the button.

Edit Marker: how to add/change markers of your results



To add or edit a marker of an existing measurement enter the main menu and scroll down with the

button to "edit marker".

You are able to choose 5 markers for the same measurement. Confirm the selection with the

button.



The last measurement with time and date is now displayed on the screen. The desired record can be choosen by navigating the up ⚠ and down ✔ buttons. When the desired record is displayed on the screen, confirm the highligted menu "Edit marker" with the ☒ button.

Edit Marker: how to add/change markers of your results

Markers

- Before meal. You set this marker before you have eaten.
- After meal. You set this marker after you have eaten.
- Sport. You set this marker when you are doing sport.
- Illness. You set this marker when you are sick.
- Special. You set this marker for a special event.

Edit Marker: how to add/change markers of your results



The list of markers appears. To add or change markers navigate with the up

and down

buttons and mark the desired markers with the

button to confirm.

To exit the menu go to "OK" and press the **O** button.



Settings saved.

Menu guidance of the *Rightest*[™] blood glucose meter GM720

In this chapter you get to know the menu guidance of your meter and how to navigate through the menus.

To navigate in the menus of the meter use the following buttons:

- To scroll up in the menu
- To scroll down in the menu
- Multifunction control button

Single click: to confirm the selection you have made

Double click: return to home screen

Long click: power off

Menu guidance of the *Rightest*[™] blood glucose meter GM720



In the main menu of your meter you can select the following sub-menues:

Records: recalling test results

Averages: recalling average calculations of test results

Edit marker: add/change markers of test results

Alarm: set alarm time

Settings: set language / date / time / volume

Control test: perform a control solution test

Records: recalling test results



The meter is able to store 1,000 test results with time, date and markers automatically. If your meter has stored 1,000 results, which is the maximum memory capacity, the oldest one will be deleted and the newest result will be stored. To recall your measured records go to the main menu and scroll down to the sub-menu "Records".



Each record can be displayed by scrolling up ▲ and down ▼ from one to the next measurement.

Each record is marked with date, time and markers.

Averages: recalling average test results



The meter is able to calculate averages. To recall the average of the measured test results you have the option to choose between 1-day, 7-days, 14-days, 30-days, 60-days and 90-days.

The average will not be calculated from the results with the control solution test.

Averages: recalling average test results



To navigate from an average result to the other, use the

▲ and ▼ buttons.







On the top line the number of calculated days is displayed. The large number with the mg/dL specification indicates the calculated average of the measurements during the time and the measured results during the period.

Averages: recalling average test results





On the bottom line the number of the calculated test results during the period is displayed.



The average function is related to the time setting. Time and date must be set correctly on your meter to enable correct average calculations.

Results: Quantity of the measurements within the chosen days.

For example, the 14-days average will show no figure, if there have not any measurements been performed during this time.

Alarm: how to set an alarm



The *Rightest*[™] blood glucose meter GM720 has four different alarms that can be individually set. To set an alarm, navigate in the main menu with the up △ and down ☑ buttons to the menu "Alarm".



Choose the selected alarm with the confirm **D** button.



To set the hour of the alarm scroll up \triangle and down \checkmark . When the correct hour is displayed, confirm the hour with pressing the \bigcirc button.

Alarm: how to set an alarm



To set the minute of the alarm scroll up △ and down ☑. When the correct minute is displayed, confirm with pressing the ☑ button.



The alarm can be set daily or only one time. Scroll up ♠ and down ▶ until the desired function is highlighted on the bottom of the display and chose the selection with the confirm ♠ button.





On the display an overview of the four alarms appears. Each alarm is specified with time and repeatability modus. If you have set the alarm, it will show the alarm symbol in the home screen.

Settings: set language



In the menu "Settings" you can select the language, set the date and time as well as chose the volume of your meter. Scroll down with the ▶ button to the menu "Settings" and confirm with the pressing the ▶ button.







In the menu "Language" you have the possibility to choose the language (English, German, French and Italian) of your meter.

To select the language of the meter you can scroll up and down and confirm your selection with pressing the button.

Settings saved.

Settings: set date



In the menu "Date" you have the possibility to set the date of your meter. Scroll down with the ☑ button to the menu "Date" and confirm by pressing the ☑ button.





You can choose two different date formats (dd/mm/yyyy) or (mm/dd/yyyy). To choose the date format scroll up ♠ and down ♥. When your desired format is displayed, confirm with pressing the ♠ button.

Settings: set date











Settings: set time



In the menu "Time" you have the possibility to set the time of your meter. Scroll down with the button to the menu "Time" and confirm with pressing the button.





You have the possibility to select from two different time formats.

Select the desired format (12-hours or 24-hours) by scrolling up \triangle and ∇ down. Confirm with pressing the \bigcirc button.

Settings: set time



The cursor will move down to the time indication. Select your desired hour with the up △ and down ☑ buttons. Confirm with the confirm ☑ button.

Two arrow-markers will flash on the minute indication. Select your desired minute with the up ♠ and down ▶ buttons. Confirm with the ♠ button.



Settings: set volume



To adjust the volume of the meter, select the sub-menu "Volume".





Now a volume symbol appears on the display. It can be adjusted with the up ▲ and down ▶ buttons. Confirm with the confirm ▶ button.

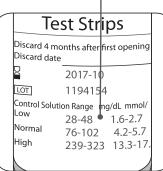
To turn off the sound of the meter, set the volume on mute.

A quality control test should be performed, whenever you want to check whether your BGMS is working properly or whenever you want to practice the testing procedure and check correct procedure.

Please use control solution tested with your system under control solution mode. If the test result is within the control solution range printed on the label of the test strip vial, that means your BGMS is working correctly.

Control solution		
range	mg/dL	mmol/L
Low Normal High	28 – 48 83 – 113 237 – 321	1.6 – 2.7 4.6 – 6.3 13.2 – 17.8

Example of control solution range printed on your test strip vial label.





Example of expiry date.



Each time you open a new bottle of control solution, write the discard date on the label. The control solution is good for 3 months after opening the bottle, or until the expiry date printed on the label, whichever comes first.

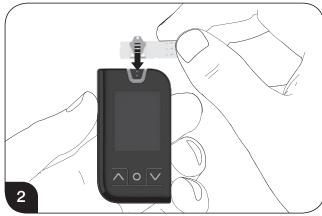
Control solution test results do not represent your blood glucose level.

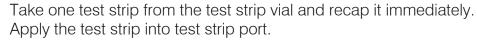


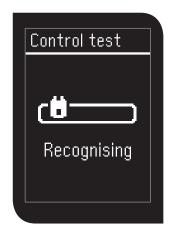
To perform a test with control solution scroll down with the ✓ button to the menu "Control Test" and confirm with pressing the ⊙ button.









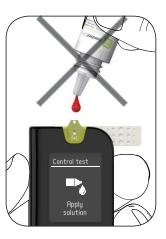


Wait for two seconds until the symbol "Recognising" disappears.







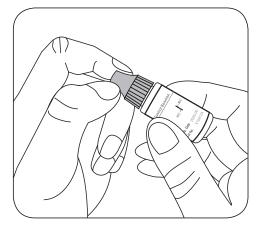


Before opening the cap of the control solution, shake the bottle well. Open the bottle and place the cap upright on the table. Drip a drop of control solution on the top of the cap. Gently touch the sample entry of the test strip onto the drop of control solution on the top of the cap.



When you hear a beep (if volume is switched on) please wait for the test result. You will see the countdown mode on the screen.





Clean the top of the cap and replace the cap on the control solution bottle.

After five seconds, the test result of the control solution test appears.

The result will automatically be marked with the control solution marker. Compare your quality control test result to the control solution range printed on the test strip vial label. This result will not be used for the average calculations of your meter.

If control solution results are out of range, your BGMS may not be working properly. Repeat the quality control test. If your control solution results are still outside the range do not use the BGMS.

Contact your local Bionime customer service.

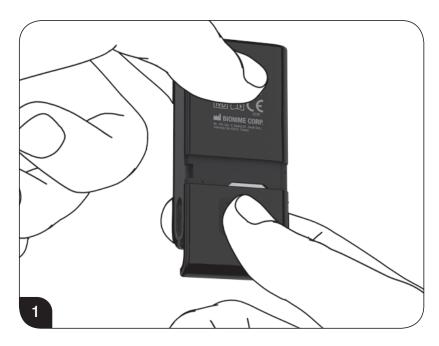
Possible reasons why your control solution results are out of range:

- Your control solution has expired or has been opened for more than 3 months.
- Your test strips have expired or have been opened for 4 months.
- Your control solution is diluted.
- The cap of the test strip vial or the control solution has been left open for a long time.
- The test procedure was not performed correctly.
- Malfunction of the meter or the test strip.
- Your control solution test has been performed out of normal temperature range (< 6 °C and > 44 °C resp. < 43 °F and > 111 °F).

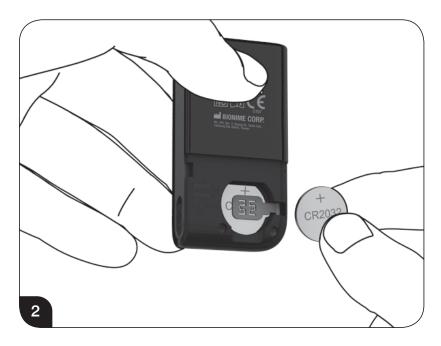


- Your control solution test results will not be included in the average reading calculations, but can still be recalled. The control solution test result will be marked with the "CS" symbol on the screen.
- The suggested temperature range for the control solution test is 6 44 °C (43 111 °F).
- Do not drip the control solution directly from the bottle onto the sample entry of the test strip. The reagent on the test strip could be sucked into the bottle of control solution and could cause the solution's degeneration. Doing this could potentially contaminate the meter via the test strip port.
- Do not touch the nozzle of the control solution bottle. If you have touched it, please clean it carefully with water.

Your meter is delivered with two CR2032, 3 volt batteries installed. Two new batteries will provide power to perform about 600 tests under normal circumstances. To install the batteries, proceed as follows:



To insert/change the batteries of your meter, move the cover on the backside of the meter downwards.



Remove the old batteries.



Install the first battery. Be sure to insert the battery the correct way with the + symbol up.



Close the contact flap and install the second battery.



Close the cover on the back side of the meter. Move the cover upwards.

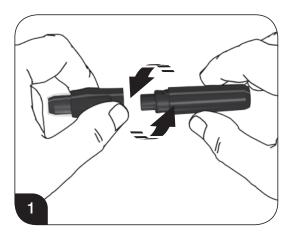


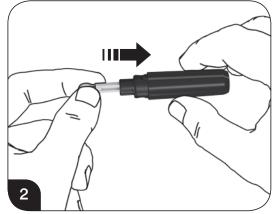
When changing the batteries without turning off the meter first, the start-up procedure has to be repeated.
Changing batteries when meter is turned-off, meter will not reset for one minute.
Measurements will not be deleted when changing batteries.

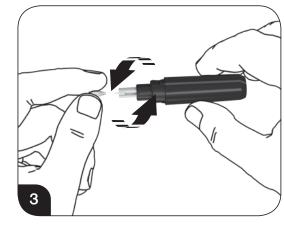
Rightest[™] lancing device GD720



Handling of the $Rightest^{TM}$ lancing device GD720



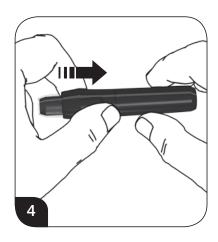


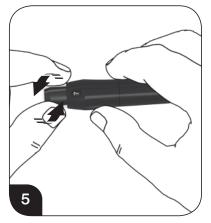


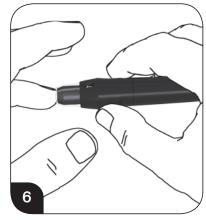
Take off the depth-adjustable cap by turning smoothly in opposite directions. Insert a new disposable lancet firmly into lancet carrier.

Twist off and set aside the protective cover of the disposable lancet.

Handling of the $Rightest^{TM}$ lancing device GD720









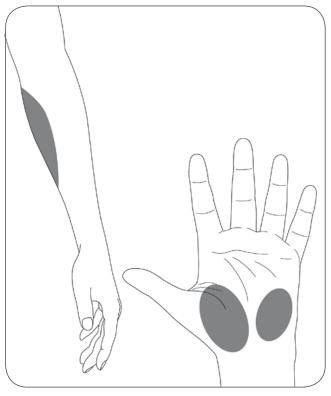
Replace the depth-adjustable cap by smoothly turning into lock position.

Choose the penetration depth by turning the cap. 1–3 for soft or thin skin; 4–5 for average skin; 6–7 for thick or calloused skin.

Place the finger against the lancing device and press the safety button.

Press your finger smoothly on the cap. The lancing device automatically loads and releases. No priming necessary.

Alternative site testing (AST)



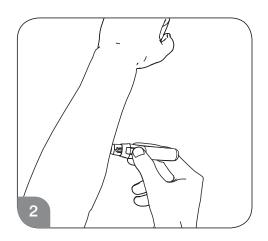
The AST function can enable to test the blood glucose on other sites than the fingertips and can benefit to avoid the repeated pricking in the fingertips and reduces the pain.

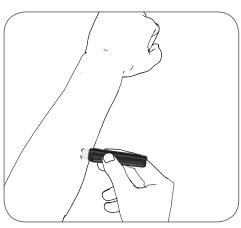


Select the clear AST cap to perform a measurement on an alternative site testing.

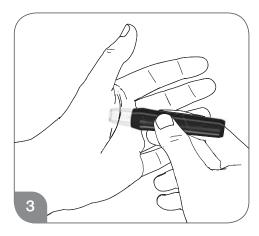
AST cap can be ordered at your local customer service. Please contact your local Bionime customer service.

Alternative site testing (AST)





Massage the puncture area of the palm or forearm for a few seconds and immediately after massaging the puncture area, press and release the lancing device with the clear cap against it.



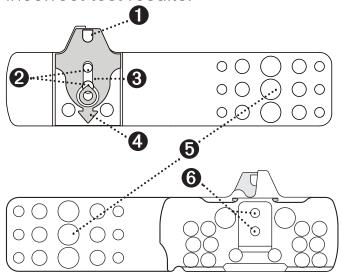
Continue holding the lancing device against the puncture site, and gradually increase pressure for a few seconds until the blood sample size is sufficient.

Alternative site testing (AST)



- The blood glucose test results of blood samples taken from different sites may vary in certain conditions, such as rapid changes in glucose levels following a drink or a meal, an insulin dose or exercise. In these cases, only the fingertip should be used.
- DO NOT test on the palm or forearm if you are testing for hypoglycemia (low blood glucose) or hypoglycemia unawareness.
- Fingertip samples can show rapid changes of glucose faster than palm or forearm samples.
- As the blood flow taken from forearm or palm is slower than from the fingertip, we recommend using the lancing device with clear cap (AST cap) for testing at sites other than fingertip.

The meter must only be used with **Rightest**[™] blood glucose test strips GS720. The use of other test strips may lead to incorrect test results.



1 Sample entry

Apply a drop of blood or control solution here. The test requires only 0.7 μ L of blood.

2 Gold electrodes

Electrochemical sensor.

3 View window

This window is yellow before applying blood sample. It gradually turns red as it fills with blood.

4 Indication symbol

Insert test strip with indication symbol upfront and down towards meter.

5 Hand bar

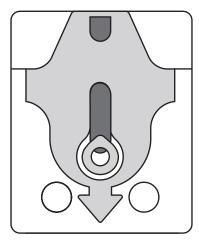
Grip here to insert test strip into meter.

6 Electrode contacts

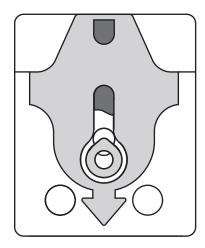
Sensing signal output termibals.



- Recap the test strip vial immediately after taking out the test strip.
- Do not reuse test strips. Test strips are intended to be used only once.
- Do not use expired test strips.
- Record the date of opening a new test strip vial for the first time.
 Discard the vial of test strips 4 months after the first opening.
- Store the test strips in a cool (4 °C 30 °C resp. 39 °F 86 °F) and dry location (< 90 % relative humidity). Do not expose to heat or direct sunlight.
- If the meter and test strips are exposed to considerable temperature variation, please wait 30 minutes before measurement.



Make sure your blood sample covers the whole area of the view window to get an accurate test result.



An insufficient blood sample can result in an error message (see page 66). If this occurs, repeat the test with a new test strip.



- Check the expiry date printed on the test strip vial every time you use a test strip.
 Do not use expired test strips.
- Use each test strip immediately after removing from the vial.
- Fill the blood drop only to the sample entry of the test strip.
- Please do not drip or inject the blood sample directly onto the sample entry of test strip using a syringe. Doing so may contaminate the meter or cause damage.

Precautions

- Before using the BGMS to test your blood glucose, please read the instructions for use carefully.
- The meter must only be used with *Rightest[™]* blood glucose test strips GS720 and *Rightest[™]* control solution GC700. The use of other test strips or control solutions may lead to incorrect results.
- If the meters and test strips are exposed to a considerable temperature variation, please wait 30 minutes before performing the measurement.
- Dispose of used batteries properly according to your local regulations.
- Please note that the BGMS contains small parts (e.g. test strips) which are a potential choking hazard for children.
- Do not allow water to enter the meter. Never immerse the meter or hold it under running water.

Precautions

■ The minimum blood sample size for testing is 0.7 μ L.



■ Please take a minimum of 0.7 μ L to perform the test on the BGMS. A blood sample size above 3.0 μ L might contaminate the test strip port and the meter. Make sure your blood sample covers the whole area of the view window to get an accurate test result. A sample size below 0.7 μ L may lead to an error message (see page 65). If this occurs, repeat the test with a new test strip.

Limitations of the *Rightest*[™] blood glucose meter GM720

- The BGMS is not intended for serum or plasma testing. For capillary, venous, arterial and neonatal whole blood testing only.
- Inaccurate test results may be obtained at an altitude of more than about 3,048 meters (10,000 feet).
- Severe dehydration may cause inaccurately low results.
- The glucose test may be invalid in the presence of abnormally high concentrations: Ascorbic acid ≥5 mg/dL (0.28 mmol/L) Xylose ≥20 mg/dL (1.33 mmol/L) Uric Acid ≥20 mg/dL (1.19mmol/L).
- If the *Rightest*TM blood glucose meter GM720 and *Rightest*TM blood glucose test strips GS720 are exposed to a considerable variation in temperature, please wait 30 minutes before measurement.

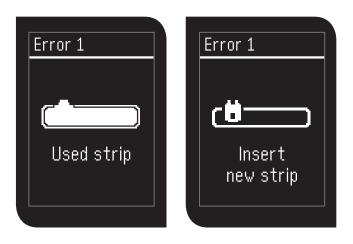


- Do not use this meter close to strong electromagnetic radiation sources, in order to avoid interference with normal operation.
- Keep the meter free of dust, water or any liquid.

Maintenance and cleaning the meter

- 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 the meter is dropped or damaged, perform a quality control test (see page 39) before doing a blood glucose test to insure that the meter is still functioning correctly.
- Clean the outside of the meter with a damp cloth and mild soap or detergent.
 Do not wet the test strip port.
- 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.

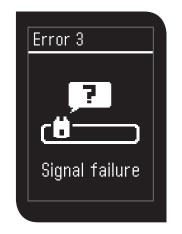


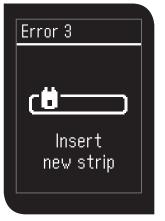
You have inserted a used test strip. Please insert a new (unused) test strip.



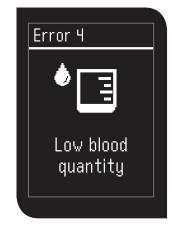


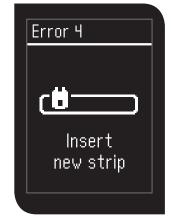
Your BGMS is not functioning properly. Please call the nearest service center.



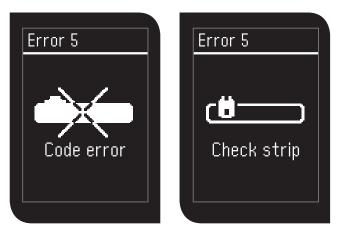


Insert a new test strip.

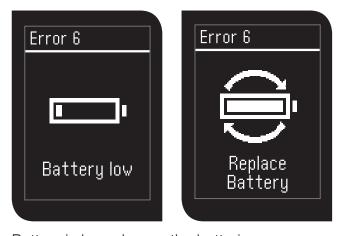




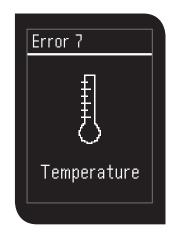
The blood sample is too small. Please insert a new test strip and repeat the measurement.

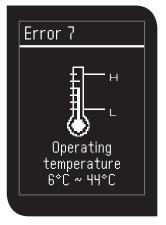


Check the test strip, the contact area may be contaminated.



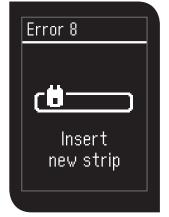
Battery is low, change the batteries.





Operating temperature is too high or too low. Go in an area with an ambient temperature between 6 °C – 44 °C (resp. 43 °F – 111 °F) and wait for 30 minutes before performing a new test.





Change the test strip.

Technical specifications

Measurement technology	Electrochemical sensor (FAD GDH)
Reference device	Olympus AU400
Measurement calibration	Plasma
Sample	Capillary, venous, arterial and neonatal whole blood
Minimum sample volume	0.7 μL
Coding	Autocoding
Measuring range	10 – 600 mg/dL (0.6 - 33.3 mmol/L)
Test time	5 sec.
Memory capacity	1,000 measurements
Power saving	on

Technical specifications

Operating temperature	6 °C – 44 °C
Operating relative humidity	< 90 %
Hematocrit	$20 \sim 70$ % when blood glucose ≤ 200 mg/dL (11.1 mmol/L),
	20 \sim 60 % when blood glucose $>$ 200 mg/dL (11.1 mmol/L)
Power supply	2 CR2032 batteries
Meter battery life	600 measurements
Meter dimension	71.5 * 39.5 * 14.0 mm
Meter weight	50 ± 5 g
Monitor	LCD display
Meter storage conditions	-10~60 °C(14~140 °F)
Test strip storage conditions	$4\sim30~^{\circ}\text{C}~(39\sim86~^{\circ}\text{F}), < 90~\%$ relative humidity

Disposing of *Rightest*[™] blood glucose meter GM720, blood glucose test strips GS720 and lancets



- During blood glucose measurement, the meter may come into contact with blood. Used meters therefore carry a risk infection. Please dispose your used meter after removing the batteries following the disposal regulations applicable in your country. For information about correct disposal, please contact your local authority.
- Used test strips and lancets are potentially infected. Please dispose the used test strip and/or the puncture-proof or biohazard container for your used lancets according to your local regulations.

Warranty

The manufacturer warrants that your *Rightest*™ blood glucose meter GM720 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*™ blood glucose meter GM720 that has been altered, misused, tampered with or abused in any way.

This warranty applies only to the original purchaser of the *Rightest*[™] blood glucose meter GM720.

Please complete and return the enclosed warranty card to your local Bionime affiliate. This warranty does not apply for any damage caused by the use of other test strips than *Rightest*TM blood glucose test strips GS720.

Customer service

We are keen to provide a comprehensive service to our customers. Please review all the instructions to ensure that you are performing the steps correctly. If you have any questions, or in the event of problems with the *Rightest*™ GM720 products, please contact your local Bionime customer service.

Customer service

Description of used symbols

	Manufacturer	EC REP	EU Representative
IVD	For in vitro diagnostic use	2	For single use only
\square	Use by		Temperature limitations
STERILE R	Sterilized using irradiation	<u> </u>	Caution (consult instructions foruse and warnings)
CE	CE Mark	CE 0197	CE Mark with number of Notified Body
Ţį	Consult instructions for use	LOT	Lot number
REF	Reference number	SN	Serial number
	Biological risks		WEEE

Manufacturer

Rightest[™] blood glucose meter GM720, *Rightest*[™] blood glucose test strip GS720, *Rightest*[™] control solution GC700

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

The products comply with In Vitro Diagnostic Directive 98/79/EC (CE 0197).

EU Representative: Bionime GmbH, Tramstrasse 16, CH-9442 Berneck, Switzerland

Rightest[™] lancing device GD720

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

Product complied with Medical Device Directive 93/42/EEC

EC-Rep: Bionime GmbH, Tramstrasse 16, 9442 Berneck / Switzerland

Disposable Sterile Lancets:

Manufacturer: Product complied with Medical Device Directive 93/42/EEC (CE 0197).

EC- Rep: SteriLance Medical (SuZhou) Inc.

No.68 LiTangHe RD, XiangCheng, SuZhou, JiangSu 215133, P.R. China

EMERGO EUROPE, Molenstraat 15, 2513 BH The Hague, The Netherlands